ENVIRONMENTAL EFFECTS ON INCIDENCE OF FALLS IN THE HOSPITALIZED ELDERLY

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To the Dean of the Graduate School:

Dissertation/Theses signature page is here.

To protect individuals we have covered their signatures.

DEDICATION

To my parents, Mr. David C. Thiam and Mrs. Camila Apiado Thiam,
thank you for being my first teachers and instilling the love and quest of knowledge.

To my husband, Mr. James Wiley Cozart, Jr.
thank you for allowing me to fly and yet pulling me down to earth at those precarious times. You are my true-blue Texan.

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thank you for believing in me. Your enduring love and faith fills my spirit.
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ABSTRACT

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ENVIRONMENTAL EFFECTS ON INCIDENCE OF FALLS
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The aim of this experimental study was to measure the effectiveness of a primary prevention environmental fall intervention using a Fall Prevention Room (FPR) to reduce falls in an inpatient setting. FPRs were equipped with various fall prevention devices including; low beds, shower mats, non-skid double sided socks, non-skid slippers, quick-drying non-skid shower slippers, floor cushions, hipsters, and bed alarms. The study employed a two-group randomized block design that examined the difference in the proportion of falls between the experimental and control groups. The sample was drawn from hospitalized patients, aged 50 or older housed in a combined neurology and rehabilitation unit, who scored 45 and greater on the Morse Fall Scale, and were considered at high risk for falling. One hundred twenty participants were conveniently recruited, 111 participants consented, 64 participants (58 %) completed the study, and forty-seven (42 %) participants were lost to early discharge or transfer. Instruments used included an Equipment Safety Checklist, a Hospital Fall Incident Report Form, and patient self-report of falls. Findings revealed that participants were primarily male (97%), white (56%), or black (38%), with a mean age of 64 years *(SD = 8.69).* There were a total of four fallers among the 64 participants. One was in the experimental group and three

were in the control group. A one-tailed Fisher's Exact Test revealed no differences between the two groups in the proportion of falls ($p = .306$, $N = 64$, $p < .05$). Lack of significance can be largely attributed to the small percentage of fallers in the sample. The study needs to be replicated with a larger sample to determine whether this environmental intervention is indeed effective at reducing fall rates. FPR may yet facilitate achievement of the ninth goal of The Joint Commission namely, to "reduce the risk of patient harm resulting from falls" and achievement of Healthy People 2010, 15th goal namely, to "reduce death from falls".

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CHAPTER I

INTRODUCTION

The repertoire of varying fall prevention modalities and the escalating cost of medical injuries and legal liabilities resulting from fall incidents demanded practical and critical strategies for primary prevention intervention. An environmental prescription called a "Fall Prevention Room" (FPR) was a technological and evidence-based innovation that addressed quality care, improvement of the patient's quality of life and cost containment in the hospital setting. The ninth patient safety goal for hospitals stated by The Joint Commission (2008) is to "reduce the risk of patient harm resulting from falls" (p. 1). Fostering patient safety through environmental manipulation and a primary prevention intervention addressed this goal. This intervention also addressed the 15^{th} focus area of Healthy People 2010 (2009) with a goal to "reduce injuries, disabilities, and deaths due to unintentional injuries and violence" (p. 3) along with a secondary objective which is to "reduce death from falls", (p. 28).

Problem of Study

The research problem identified for this study was: How effective is a structured environmental intervention that utilized FPRs at reducing unanticipated falls among elderly hospitalized patients, who were at high risk for falls in an acute care Veterans Affairs (VA) facility?

Rationale for the Study

A "longevity revolution" is occurring in the country. The latest United States Department of Health and Human Services, Centers for Disease Control and Prevention (CDC) (2009) report projects that in the year 2030, the geriatric population will surge to an estimated 70 million seniors. The geriatric boom will have an adverse consequential effect on economic costs, medical care, nursing services, and public health programs. Among the adverse effects of aging, include falls and subsequent hospitalization due to injuries incurred from the fall event itself.

The incidence of falls among older Americans is troubling. The CDC (2009) reports that an estimated 33 % of the geriatric population fall annually. A physiological and unanticipated or accidental fall is considered an "adverse event" (Considine & Botti, 2004, p. 21) in acute care settings and 62 % of these adverse events are caused by falls (Carson & Cook, 2000). The CDC (2009) also cites that unintentional falls trigger the foremost reason for 14, 900 traumatic deaths in those aged 65 and older. Moreover, about 1.8 million older Americans have sought emergent care from associated trauma caused by falls and greater than 433,000 of these cases have eventually needed further confinement (CDC, 2009).

Among non-fatal injuries, hip fracture is the leading cause, and commonly the most serious type of fall-related injury in the elderly. Albeit, Hwang (1999) asserts that the aging population is prone to developing approximately 87 % of all fractures due to accidental falls. The National Center for Health Statistics (NCHS) (2008) reported well over 320, 000 cases of hip fractures in hospital admissions in 2004. Consequently, older adults admitted for hip fractures were unable to revert to their previous independent condition and dwelling place (Hwang, 1999). Moreover, Jager and associates (2000) posit that traumatic brain injury in the elderly is primarily from accidental falls and, resulted in a 46 % fatality rate in 2000 (Stevens, Corso, Finkelstein, & Miller, 2006).

Salgado and colleagues (2004) contend that in medical institutions, falls occur primarily in geriatric units with medical and surgical units close behind. In-patient hospital falls as reported ranged from 2-12 per 1,000 bed days of care (BDOC) (Kimbell, 2002; Hitcho et al., 2004). The American Geriatrics Society (AGS) (2001) cites that accidental falls in hospitals is nearly threefold as compared to residential falls among age 65 and older adults.

Fifty percent of falls in the hospitalized elderly occurred during toileting activities such as going to the bathroom (37 %) or transferring from portable commode back to the bed (6 %) (Hitcho et al., 2004) Additionally, hospitalized in-patient fallers (29 %) used ambulatory equipment at home prior to admission, but were not using any assistive apparatus at time of falling. Most notably, the same group (Hitcho et al., 2004) cited that 79 % of falls are un-assisted and 85 % transpired in hospital rooms during late afternoon (59 %).

Accidental falls and fall-related ill effects painted quite a daunting picture for the elderly particularly among aging military veterans. In 2006, Quigley, Palacios, and Spehar conducted a prevalence study about war veterans' propensity for falls. Among its findings included the aging statistics for veterans, which were 25 % higher than non-military population. Of critical importance was the finding that institutionalized elderly veterans scored at an increased-risk for predictable accidental falls, particularly in acute care, intensive care, or chronic care settings. In a 2005 retrospective survey of VA Ambulatory Events Database, the Luther group reported an estimated quadruple increase of outpatient care utilization by veterans due to fall-related problems. Veteran demographics showed 65 and older years of age presented to the emergent care setting with multiple co-morbidities. Although initial care was rendered in the Emergency Units or Ambulatory Clinics, the resulting injuries sustained from falls continued on to other health care services such as the operating theater and rehabilitation department.

Falls also played a larger role in medical expenditures in the elderly. Findorff, Wyman, Nyman, and Croghan (2007) studied the direct medical care expenditure of a fall incident with a price tag ranging from $ 63 to $ 85,984. The average cost of an injury-related fall occurrence is $ 6,606 with a median cost of $ 658. Stevens and colleagues (2006) reported an even more portentous health care expenditure of $ 179 million for deaths due to falls and $ 19 billion for fall-related trauma in 2000.

Major studies had found that fall incidents could be substantially lowered by initiating and implementing various modalities for fall reduction (Chang et al., 2004;

Haines, Bennel, Osborne, & Hill, 2004). According to Close and colleagues, (1999) environmental alteration could significantly reduce falls in acute care settings. However, there existed a healthy controversy in regards to a single intervention versus a multi-layered program for fall prevention (Tinetti, 2003). Likewise, trials that examined environmental prescriptions had sparse samples, problematic designs, and yielded no profound difference in the results (Eagle et al., 1999; Fischer et al., 2005; Haines et al., 2004); Vassallo et al., 2004).

On the other hand, studies that recruited a larger number of participants had also fared poorly in reinforcing environmental intervention singularly as a valid and reliable fall reduction modality (Healey, Monro, Cockram & Heseltine, 2004; Close et al., 1999; Sattin et al., 1998; Vassallo et al., 2004). However, as one dimension of a multi-factorial fall prevention program, individual elements of environmental modification have tentatively supported diminution of fall rates in elderly hospitalized patients (Cumming, 2002; Gillespie et al., 2002; Lane, 1999).

While an extraordinary number of studies had been conducted in regards to incidence of falls and protocols to prevent falls targeting intrinsic and extrinsic risk factors, the FPR in its totality had not been examined independently. A causal relationship between FPR - a specific environmental prescription, and reduction of the number of falls in acute settings among high-risk for fall elderly patients had not been identified in the literature. Thus, this study examined whether specialized fall prevention rooms affected the number of falls in elderly patients admitted in a medical-surgical unit at a U.S. VA hospital.

Theoretical Framework

Neuman System's Model (NSM) provided the theoretical foundation for this investigation. NSM focuses on the integrity and stability of the whole system of interest as it interacts with the environment. This model defines health as optimal client system stability or the best possible wellness state at any given time (Neuman & Fawcett, 2002). According to Neuman and Fawcett (2002), "A system acts as a boundary for a single client, a group, and even a number of groups. The client system interacting with the environment delineates the domain of nursing concern" (p. 3). The core component of the system consists of the basic structure and energy resources that are surrounded by three critical lines, called the line of resistance, normal line of defense, and flexible line of defense methodically arranged in a concentric circle. At the innermost center of the core is the client of interest that is in a relationship continuum with surrounding environmental factors that may potentially cause a health problem due to stress interaction, or may actually incur critical adverse manifestations, or could even influence the system's recovery post-treatment phase. The lines of resistance and the normal line of defense in synergy with the system's holistic factors, (physiological, psychological, socio-cultural, developmental, and spiritual) control the client's responses to stressors (Figure 1).

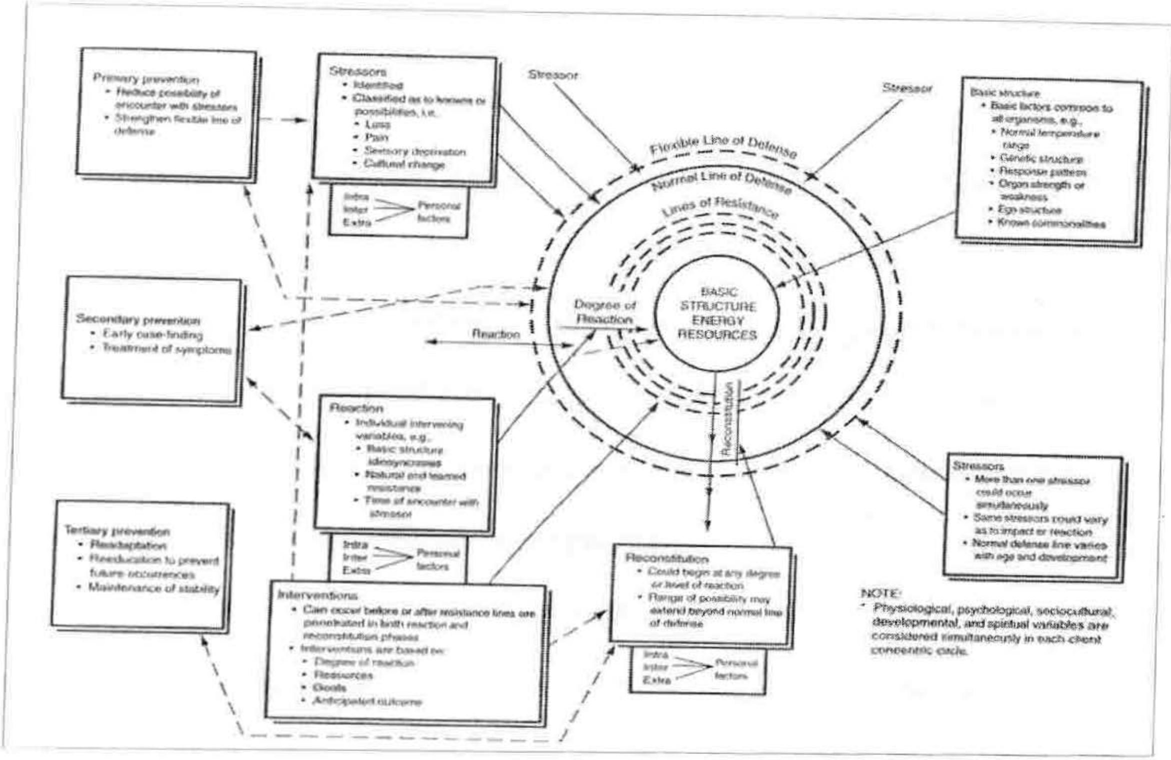

Figure 1. Neuman Systems Model of Nursing by Betty Neuman, 2005. From Neuman Systems Model Trustee Inc., http://neumansystemsmode.org//NSMdocs/nsm_ powerpoint_overview.htm. Reprinted with permission.

McEwen and Wills (2002) identified the NSM as "prescriptive in nature" (p. 144). This study prescribed an environmental modification – the FPR. The FPR was utilized as an environmental intervention in alleviating accidental falls in hospital settings. The relationship that was examined in this study was the external environmental influence, represented by the FPR, as a primary prevention intervention that affected the client as a system, from its basic structure to its lines of resistance and two lines of defense (flexible and normal).

The physiological variable might be the most vulnerable domain that would be affected by falls and related injuries that might ensue. The human body might show actual signs of trauma sustained from a fall event that could be labeled as a stressor. Neuman (2002) defined a stressor as "any environmental force which can potentially affect the stability of the system" (p. 17). In this instance, the environmental stressor was the unanticipated accidental fall event that originated from the patient's admission to the hospital. It can be identified as an external environmental stressor contributing to falls as opposed to the internal environment of the patient.

The flexible line of defense is described as an "outer, broken circle surrounding the normal (solid) line of defense and acts as a protective buffer system for the client's normal or stable state" (Neuman & Fawcett, 2002, p. 17). The FPR represented the flexible line of defense through its role as an environmental protective buffer for fall hazards in the hospitalized patient to protect the normal line of defense. A fall event might act as a "single stressor that had the potential for reducing the effectiveness of this buffer system" (Neuman & Fawcett, 2002, p. 17), which could then penetrate the normal line of defense, and subsequently, activate the lines of resistance to stabilize or de-stabilize the system's core integrity. Accordingly, when the patient's core integrity was compromised by a fall event and fall-related injury that might ensue, nursing interventions were planned to return the basic structure to optimal wellness. The goal of nursing in NSM is to assist the maximum level of health through "retention, attainment, or maintenance of client system stability" (Neuman & Fawcett, 2002, p. 3). The system's stability was represented by the incidence of falls that were prevented from occurring. Thus, using the FPR as a *flexible line of defense* in conjunction with *primary prevention intervention* against accidental falls and fall-related injuries, representing the external environmental *stressors* within the NSM framework would provide the system's *stability or wellness* by reducing incidence of falls as exemplified by the *normal lines of defense* and *lines of resistance*, and is congruent with this study.

Assumptions

The following assumptions are relevant to this investigation and were drawn from the assumptions posited by Neuman in the NSM (McEwen & Wills, 2002):

1. Each client/client system has evolved a normal range of responses to the environment that is referred to as normal line of defense. The normal line of defense can be used as a standard from which to measure health deviation (p. 156).
2. Primary prevention relates to general knowledge that is applied in client assessment and intervention, in identification and reduction or mitigation of possible or actual risk factors associated with environmental stressors to prevent possible reaction (p. 156).
3. When the flexible line of defense is no longer capable of protecting the client//client system against an environmental stressor, the stressor breaks through the normal line of defense (p. 156).

Hypothesis

The following hypothesis was formulated for this study:

Hospitalized patients, age 50 or older who scored greater than 45 on the Morse Fall Scale (MFS) will report lower falls during a seven-day hospital stay when assigned to a Fall Prevention Room (FPR) than comparable hospitalized patients assigned to a regular room (RR).

Definition of Terms

The following key terms were defined for the purposes of this investigation:

1. *Fall:* "Loss of upright position that results in landing on the floor, ground or an object or furniture or as a sudden, uncontrolled, unintentional, non-purposeful, downward displacement of body to the floor or ground and/or hitting another object like chair or stair. This does NOT include patients assisted safely to a lower surface by another individual". (Michael E. DeBakey Veterans Affairs Medical Center. (2002). *Fall Prevention and Management Standard of Care.* Houston, TX, p. 1). Fall was operationally defined as a calculated score of the number of falls sustained and gathered from patient self-report and interview conducted once daily by the principal investigator and corroborated by subsequent documentation of a hospital fall incident report generated by the staff whenever a fall occurred within the unit.
2. *Fall Prevention Room (FPR):* A "portion of space within a building or other structure, separated by walls or partitions from other parts" (Random House Webster's Unabridged Dictionary, 1998, p. 1670), allocated to prevent fall events. Fall Prevention Room was operationally defined as the calculated score of 51 environmental fall prevention medical devices and equipments condensed into the

Equipment Safety Checklist (ESC) from the *Falls Toolkit* of the U.S. Department of Veterans Affairs, National Center for Patient Safety (NCPS) (2004) (see Appendix A1). The environmental fall prevention elements contained in the ESC were assembled from Morse (1997) and BRODA's maintenance manual (BRODA, n.d.).

3. *Hospital Stay:* The first seven days of hospitalization counted from the date of admission, regardless of what time of day or night the patient was admitted into the study unit. This was measured by bed days of stay (BDOC); one day was equivalent to 1-24 hours, or one week was equivalent to seven days.
4. *Morse Fall Scale (MFS):* A screening instrument that assesses a patient's vulnerability for falls scored in varying degrees namely; low, medium, and high (Morse, 1997). It is a quick and easy estimate of a patient's risk of falling as scored by six variables used widely in acute care settings, both in the hospital and long-term care inpatient settings. This was used to determine participant eligibility for high-risk (scored as 45 and over) for falls in this study.

Limitations

There are theoretical and design limits of this investigation including:

1. Generalizability of the findings is limited by inclusion and exclusion criteria of the study.
2. The follow-up period of seven days might have limited the effects of hospitalization, either for short or long-term effects on the incidence of falls.
3. Measurement effects might have influenced the study, in particular - the screening

instrument (MFS) might inadvertently become a type of fall intervention for the patients at high-risk for falls that might subsequently influence the participants to feel heightened awareness for their propensity for falling and thus, might contribute to the potential benefits and effectiveness of the FPR.

4. Other threats might have biased this study such as, expectancy effects (Hawthorne effect) and novelty effects. The physical infrastructure of a FPR might be viewed as a technical innovation due to its evidence-based design, and could possibly provide a false sense of fall security and safety for participants and hospital personnel.

Additionally, the staff might be forewarned and very likely might give preferential treatment to those they had identified as high-risk for falls upon initial fall assessment using the MFS, and thus, would be inclined to offer timely assistance for toileting or transfer activities, which would subsequently reduce the likelihood of fall occurrences.

Finally, experimenter effects might have presented a threat. There were two other data collectors along with the principal investigator; namely, an experienced case manager who had done quality improvement on hospital fall prevention, and an eminent clinical researcher with fall prevention expertise.

Summary

Incidence of falls in the acute care setting presents a continuing dilemma for bedside clinicians, risk management, staffing, and administration even as the aging population escalates in hospital admissions along with various co-morbidities of medical conditions and acuity of patient illness. An evidence-based design of a fall prevention room might provide promise to prevent accidental falls and mitigate fall-related injuries, along with consequent economic, health-care, social, and judicial costs. Evidence-based fall prevention modalities had been initiated and practiced in varying degrees of success and effectiveness, that could trim down the human, fiscal, medical, and structural physical resources of the nation as well as the greater global health care industry.

CHAPTER II

REVIEW OF LITERATURE

This chapter evaluates, summarizes, and synthesizes a plethora of publications about the state of the science on fall incidence and fall preventive strategies in the hospitalized elderly patients. A comprehensive review of unintentional or accidental falls and fall prevention publications was conducted using electronic keyword and Boolean search techniques as well as manual strategies. Multiple nursing, medicine, and physiotherapy databases were electronically searched. Databases that were accessed included Web of Science, MedLine, Cumulative Index to Nursing and Allied Health (CINAHL), On-line Dissertations, ERIC, Physiotherapy/PEDro, Ulrich's, and Cochrane.

Journal articles in 2008 and 2009 unavailable electronically were manually extracted. The reference lists of articles were also reviewed to obtain additional manuscripts that did not surface upon initial computerized exploration. Keywords used were based on the critical variables of the study and included; elderly, aged, older, military veterans, and geriatric for the target population. For the study setting, keywords included hospital, medical, and geriatric units, as well as, acute and long-term care settings. For the dependent variable, keywords used were accidental falls, unintentional falls, fall incidence, fall rates, and hospital falls. Keywords used for the study intervention were fall prevention, fall reduction, and fall safety. Research focusing on environmental safety devices and medical equipment commonly used in the acute care setting was also surveyed. Keywords used included: a) medical equipment, such as low-beds, bedrails, bed alarms, grab bars, bed side tables, geri-chair, hipsters, non-skid socks, fall-alert sign; b) ambulatory or assistive devices, such as wheelchairs, scooters, walkers, or canes; and c) structural elements, such as non-skid floorings, floor waxes, floor cushions, bathroom mats, or lighting. Additional searches were conducted using the following terms; environmental fall hazards and fall risk factors. Truncations and Boolean words were also used in the search process. Limitations for the search were specified as; English for language, time span ranged from 1985-2009, human participants of both genders, aged: 50 plus years, clinical trials, full-text articles, and meta-analyses.

Research on incidence of falls and fall prevention is not exactly virgin territory. Due to the magnitude of published literature on accidental falls and/or fall prevention programs, requisite inclusion criteria for this paper were further delineated to include fall studies in hospital settings in the U.S. and in other countries with older adult participants treated with multiple composite of environmental approaches for fall prevention. The author made critical decisions and selections for this review by focusing on the relevance, association, and congruency of the articles in relation to the independent variable, environmental safety designs in particular – the in-patient's room and adjoining bathroom, fall events, hospital setting, and geriatric population for this investigation.

The literature review commenced with definitions of fall followed by a discussion of those at risk for falls. Contributing risk factors are categorized into extrinsic and intrinsic factors. An elaboration of extrinsic risk factors with particular emphasis on various environmental and structural safety medical equipment and devices are then detailed. In addition, discussions of the effects of hospitalization and technological innovations in regards to incidence of falls are presented. Furthermore, intrinsic factors such as age, gender, and chronic medical conditions are also explained in relation to fall occurrences. This is followed by a description of fall prevention strategies with an in-depth review of current experimental studies that have tested various fall prevention strategies. A discussion of selected meta-analyses concludes the literature survey.

Definitions of Fall

A concise and consistent definition of fall was essential to provide a baseline understanding of the concept. Numerous definitions of fall were discovered in the literature. A comprehensive meta-analysis of fall definitions (Hauer, 2006) was found in random controlled trials (RCTs). Of the 90 papers reviewed, nearly half (N = 44) supplied no definitions of the concept and the other half presented considerable variations in the definition of the term fall. Table 1 (see Appendix B) presents a partial listing of fall definitions and comparisons of fall definition to this research. It provides ample justification for a nursing consensus to construct a uniform and standard fall definition that could be used in any health care setting independent of time and risk factors.

Principal elements that provided the baseline for the formulation of the fall definition for this study included: (a) an incident of time that presented as sudden, unexpected, involuntary, inadvertent, unplanned, and/or unanticipated event; (b) an orthostatic change that occurred from an original upright vertical stance or posture, and ending downwards on a lower level or surface; (c) a directional variance that transpired from a vertical point to a horizontal position; (d) a kinetic motion that arose from a burst of dynamic motion or movement; and (e) a consequential location that happened at a particular site, place or setting such as the floor or ground. Thus, the fall definition for this study was:

> Loss of upright position that results in landing on the floor, ground or an object or furniture or as a sudden, uncontrolled, unintentional, non-purposeful, downward displacement of body to the floor or ground and/or hitting another object like a chair or stair. This does NOT include patients assisted safely to a lower surface by another individual. (Michael E. DeBakey Veterans Affairs Medical Center. (2002). *Fall Prevention and Management Standard of Care*, Houston, TX, p. 1).

Risk Factors Contributing to Falls

There are two types of environmental fall risk factors generally known to contribute to falls, which are classified as extrinsic, exogenous or external to the patient and intrinsic, endogenous or internal to the patient. Intrinsic factors were frequently used to assess a patients risk for falling, while extrinsic factors were frequently used in considering fall prevention interventions from a physical venue standpoint. The following sections discuss both intrinsic and extrinsic factors identified in the literature survey.

Intrinsic Risk Factors

Intrinsic risk factors refer to the endogenous or internal milieu within the patient system (Alexander, 2002; Fuller, 2000; Hignett & Masud, 2006; Rubenstein &

Josephson, 2006; The Merck Manual of Geriatrics, 2005). Stevens (2005) labeled intrinsic risk factors as "personal" (p. 410). The patient's intrinsic or internal environment refers to common demographic profile such as age, gender, ethnicity, marital status, education, or socioeconomic levels. It also addresses past history of falls, medical or surgical disease, physiological or mental condition, multiple medication use, surgical disease, physiological or mental condition, multiple medication use, nutritional status, ability to communicate, and cognitive functioning, which might inherently influence the internal environment of the patient.

Robey-Williams (2007) listed the uppermost 10 vital fall predictors found in the literature survey. These were; history of past falls, drugs, coordination, age, mental confusion, altered mental capacity, physical surroundings, altered ambulation or movement, impaired elimination, and increased blood pressure. According to Nevitt (1997), 65 % to 100 % geriatric patients sustained falls within a year when three or more risk factors were identified, whereas among those lacking in any risk factor the percentage was considerably lower by 8 % to 12 %. Similarly, Williams et al., (2007) endorsed this premise that when the number of risk factors identified in a patient was greater, the chances of falling for that particular patient were exacerbated.

Age and gender. Hitcho and associates (2004) found in their prospective descriptive investigation regarding the characteristics and circumstances of 200 hospital falls sustained by 183 patients, that among the two genders, male participants were more likely to fall than the female gender *(11/86 [13 %] vs. 4/97 [4 %]; $p = .03$)*. Similarly, in an earlier study, Vassallo and colleagues (2000) found that male participants fell more frequently than female participants. Other findings of the study conducted by McCarter-Bayer, Bayer, and Hall (2005) showed that the average age of fallers was 63.4 years (age range 17-96) and 50 % of the fall events occurred during toileting by patients older than 65 years old *(83 % vs. 48 %; $p < .001$).*

Effects of co-morbidities. Stevenson, Mills, Welin, and Beal (1998) conducted a descriptive study between two groups retrospectively by examining other characteristics of those who had fallen, other than the two previously known endogenous fall risk factors of chronological age and medical condition. The investigators identified 301 older participants in an 801-bed urban hospital and matched them in both age and disease process through fall occurrence reports and patient charts. The sample had considerable variability in age, from 18 to 65 years and older. Likewise, gender was unequal, with more female participants *(63 %)* than male participants *(37 %).* Study results showed five risk factors of both intrinsic and extrinsic elements. The intrinsic or endogenous factors consisted of elimination problems, need for ambulatory aid, physical inactivity, and inability to perform personal hygiene. The continent patients fell less than those who were incontinent (*11.3; CI* = *3.85, 33.05*). Bedridden participants requiring total assistance for mobility fell more than those who could independently walk (*6; CI* = *2.83, 12.84*). Lack of exercise accounted for higher incidence of falls in the geriatric group (*CI* = *1.00, 3.82*), and participants who could perform their own self-care fell more than those who needed total nursing care (*2.5; CI* = *1.23, 4.88*).

McCarter-Bayer, Bayer, and Hall (2005) also reported other intrinsic medical conditions commonly associated with falls such as depression and confusion or disorientation. For hospitalized patients, these are critical intra-stressors that may affect the normal line of defense and consequently, the individual's core structure. In fact, Vassallo, Azeem, Pirwani, Sharma, and Allen (2000) cited various internal factors contributing to falls, such as gait and balance problems, neurological and musculoskeletal conditions, psychoactive drugs, dementia, and visual difficulties.

Lane (1999) completed an evaluative retrospective seven-year study of a non-randomized conveniently selected stratified sample of 292 patients admitted in medical and surgical wards of a community hospital in Southwestern Ohio who participated in a fall prevention program (FPP). Data collection came from review of fall occurrence forms and patient records. The researcher used the "Fall Risk Assessment Profile" originally developed by three master's students (Dunlap & Mazzei, 1989; Berchtold, 1992) but with no previous validity and reliability analyses performed. This instrument tested four predictors for fall which were age, impaired cognitive ability, poor muscular functioning, and use of ambulatory medical aids. Fall risk factors that emerged from this study identified elderly fallers, 60 years old and over, with co-morbidities consisting of cognitive problems along with muscular limitations, and prior use of ambulatory devices.

Extrinsic Risk Factors

Multiple primary extrinsic risk factors had been identified including physical environment of the hospital, the hospitalization event itself, technological gadgets, and other situational factors.

Physical environment. Evidence-based literature on hospital designs reported that the structural layout could contribute to patient safety by mitigating environmental predictors of fall and adverse consequences (Zimring & Ulrich, 2004). The physical design and layout of hospital rooms did not lend themselves to fall prevention. Patient rooms were cramped and cluttered with hospital paraphernalia along with personal belongings. For example, inside the hospital room were durable medical equipments including adjustable beds, along with various usual accoutrements, such as bedrails, call buttons, bed alarm, bedside tables, chairs, mirrors, poster boards, pictures, calendars, bedclothes, and grab bars. Even assistive or ambulatory apparatus, such as wheelchairs, scooters, walkers, canes, and crutches might contribute to falls. There were also various types of flooring and surface traction that might be highly waxed and buffed, as well as uneven or slippery floor surfaces. Even personal effects worn by the patient such as the type of footwear (i. e., non-skid socks or slippers), hipsters, wrist fall alert bracelet, wrist restraints, and fall t-shirts might contribute to external variables that albeit, intended to mitigate falls might actually cause falls themselves. Other external environmental factors such as loose rugs, unstable and broken furniture, floor clutter, and even bed size height, and firmness that were quite different compared to those commonly used at home (Lueckenott, 2000; Williams et al., 2007) could also create fall conditions. Furthermore, rooms might be shared with an unknown roommate and his/her visitors. Lighting was bright and glaring. Bed controls were confused with call buttons. Adding even essential equipment such as portable intravenous (IV) pumps connected to IV solutions, portable suction machines, or dialysis machines within the confines of a typical hospital room left little space to ambulate. Furthermore, other devices that might be attached to the patient such as foley catheter or naso-gastric tube (NGT), and even well meaning get-well gifts from friends, such as flowers and stuffed animals on bedside tables made navigation precarious at best.

Halfon, Eggli, Van Melle, and Vagnair (2001) conducted a yearlong predictive survey at a Switzerland hospital about the incidence of falls and the conditions of their occurrence and correlated them to patients' fall risk factors. A review of 488 fall incident reports identified that 37 % of reported falls could have been prevented if appropriate environmental safety features were not breached. For example, environmental assistive or ambulatory devices such as wheelchairs had improper brakes, and over-bed tables were not secured. Other environmental structural variables such as slippery floor, room clutter, and inadequate illumination were also cited. Improper maintenance of hospital equipment and poor structural conditions resulted in eight percent (8 %) of reported falls. Still, more than 50 % of falls from wheelchairs or bedside chairs could have been prevented if chair straps were used and 24 % of bed-related falls could have been averted with bedrail use. Likewise, 32 % of the slips reported could have been avoided through use of non-skid footwear. Clearly, hospital falls could be precluded if environmental safety maintenance was meticulously observed and medical devices were regularly checked for safe and proper working condition.

A 2 by 2 randomized comparative study of two types of flooring, carpet & vinyl in the patient room, in conjunction with two types of exercise modalities to decrease falls among 54 consecutively selected rehabilitative patients for a nine-month period was investigated by Donald, Pitt, Armstrong, and Shuttleworth (2000) in an English hospital. Findings showed eight participants who fell (15 %) with a total of 11 falls among the four subgroups of participants. Likewise, results showed that besides one subject falling on the vinyl floor, an additional 10 participants fell on the carpet floor *(RR = 8.3, 95 % CI 0.95-73, p = 0.05).* From the clinical perspective of the number of patients who fell in the environmental type of floor covering intervention (carpet vs. vinyl), the lone faller seemed to indicate that vinyl flooring was less likely to cause falls as opposed to carpet. Remarkably, the 15 % of patients who fell was considerably lower than the 35 % baseline annual fall rate of the hospital.

The Fonda group (2006) conducted a combination of retrospective and prospective study in Australia examining a three-year period (2001-2003) of elderly in-patient fall hospital admissions. Data comparison was analyzed between the baseline year and the two years following implementation of a multifactorial fall reduction program that included among others changes in the work place and equipment safety modifications. Extrinsic environmental alterations included clutter removal in the room, non-slip toilet floor, non-slip bed mat, non-slip chair mat, and non-slip bed sheets. Other fall reduction devices used were bed sensors, bedposts for balance and transfer, fall-wrist alert, bed fall-alert sign, and electric beds adjustable to a foot off the floor. Additional environmental interventions utilized were non-glossy floor wax, magnetic devices attached to toilet doors to prevent patients' crash, more suitable seating distance from the floor, illuminated toilet seats and stickers, along with an automatic night-light. Results showed that use of electrical beds easily adjusted to a foot off the floor during bed transfers significantly lowered patient injuries associated with falls. Remarkably, there was a 19 % decline of falls per 1,000 BDOC *(12.5 v 10.1, p 0.001)* and a dramatic 77 % drop of fall-related injury rate between 2001 and 2003.

A year-long prospective experimental study by Hathaway, Walsh, Lacey, and Saenger (2001) that implemented a Fall Prevention Program (FPP), in an Australian hospital among elderly in-patients age 65 and over, found that the number of falls (N = 61) decreased and the "fallers" were those identified in the high-risk category. The FPP constituted of bedside nurses completing and scoring three categories of fall-risk for all admitted elderly patients, using a "Fall Prevention Assessment Form". Depending on the total score, a patient was identified as low (score 0-24), medium (score 25-31), or high risk (score 32-40) and particular interventions were instituted according to the degree of risk. For the high-risk patients, the environmental interventions used were green colored armband, a green sticker pasted in their chart, a non-slip mat adjacent to the bed, an electronic mobility sensor that emitted an alarm along with a paging alert.

Vassallo and colleagues (2004) conducted a year-long prospective, observational, quasi-experimental, two group study of geriatric in-patients at a rehabilitation hospital in the United Kingdom, that examined the effectiveness of a multidisciplinary evaluation with regularly scheduled case meetings utilizing the Downton fall-risk tool for fall prone patients. Interventions include fall alert identification tags for high-risk for fall patients and other environmental changes such as clutter elimination, correct use of foot support, ambulatory aids, nurse-call device, elimination appliances, and placement of patients proximal to bathrooms. Findings showed that the interventions supported a hefty difference in the fall rates *(15.3 %)*, lessened the number of fallers *(29.7 %, p 0.041)*, and diminished fall related injuries *(51.1 %, p – 0.028)*. All the above studies pointed to a need for environmental modification and a strategic fall reduction program that would focus on mitigation of external fall factors.

Hospitalization event. Hospitalization was a precarious and non-stabilizing event for any individual as it distracted from the normal activities of daily living. Neuman and Fawcett (2002) described hospitalization as an "external environmental stressor" (p. 17). Elderly patients who were already dealing with age-related conditions, and screened as high-risk for falls became even more susceptible to multiple stressors emanating from the hospital environment. Hospitals presented an unfamiliar, intimidating, and often hostile environment. Surroundings were unfamiliar, noisy and filled with strange faces and even stranger medical devices and equipment.

Bathrooms were frequent locations of patient falls during toileting and hygiene activities (Scott, 2007). Bathrooms might contain other medical appliances such as shower chairs or portable commodes that curtailed space for ample movement. Bathrooms often lacked grab bars, showers lack anti-skid floors and the floors might be uneven, wet, and/or slippery. In addition, when patients were given "bathroom privileges" (Morgan, Mathison, Rice, & Clemmer, 1985, p. 776) the risk for falls might increase. Generally, patients might share bathrooms. Thus, when one patient happened to be in the bathroom, the other patient might have to wait for his/her turn. A likely scenario might be that when a patient waiting to use the toilet could be unable to control the need for elimination, leading to risk for falling when this patient might have an accidental urine spillage. Alternatively, when the patient inside the stall attempted to hurry up so the other patient could have his turn might likewise hastened fall incidents. According to Purdy (2004) as cited in Krauss et al., (2005) this was called "elimination fall – a fall related to the need to use the toilet" (p. 1) and those who fell due to toileting needs were particularly vulnerable to bodily harm. In fact, Krauss et al., (2007) reported bathroom falls were correlated to physical trauma (*aOR, 1.46 [95% CI, 1.06-2.01*]).

Meanwhile, a prospective population-based survey among 2,186 hospitalized elderly in Iran (Abolhassani et al., 2006) to identify fall occurrences and resulting hip trauma reported 116.3 yearly incidence of fall-related trauma and 30.4 yearly incidences of broken hips associated from these falls per 100,000 person-years. Among the elderly, age 50 years and older, the study showed 237.1 yearly occurrence rate of fall-related trauma and 93.6 yearly incidence of hip fractures per 100,000 person-years. Seventy-one percent of fall-related trauma along with 76 % of broken hipbones happened within the confines of the home environment that subsequently resulted in hospital admissions.

Length of hospitalization. A related contributing factor to falls was the duration of hospital stay. It could be classified as an indirect exogenous risk factor because it could cause an adverse effect. Lengthened hospitalization was found to contribute to fall occurrences. The patients who fell more often stayed in the hospital for nineteen BDOC compared to those who stayed for shorter duration (Stevenson, Mills, Welin, & Beal, 1998). According to Schwendimann et al., study (2006), findings showed a significant decrease of initial fall within four days of confinement in the experimental group. Williams and associates (2007) substantiated this assertion by citing that falls occurred more frequently during the first seven days of admission and during the third week, perhaps from implementation of physical therapy and restorative regimen. In contrast, findings from Vasallo and partners (2004), showed a significant increment of falls in the treatment group per 1000 BDOC, though they ran a risk calculation ratio that ultimately failed to reject the null hypothesis. The threat of a spillover measurement effect due to the closeness of the two groups might warrant a possible argument to the rejection of the null hypothesis. Again, findings from this study must be interpreted with prudence primarily for generalizability because of the effect of heterogenous variables of age and gender, even though the investigators instituted matched or paired control. Furthermore, incident reports might not have reflected each circumstance of falls when no one had actually witnessed the fall event.

Effects of assistive technology. Technological innovations had contributed greater conundrum to an already overburdened and understaffed health care system. Although, current technological tools reflected the progress of the electronic age for the sicker and aging population than they intended to serve, these medical paraphernalia might also bring on inherent hazards in their utilization. The Nelson group (2004) cited examples of medical technologies aimed at easier mobility and transfer to aid the elderly move about in their activities of daily living within the confines of their lived-in environment, yet also directly curtailing falls and associated trauma. These medical inventions encompassed ambulatory or assistive devices such as wheelchairs or scooters with built-in safety elements, fall sensors, so-called "intelligent walkers", and hip shields. To prevent patients from incurring bed rail injuries resulting from false imprisonment or entanglement between the bed mattress and rails, there are now newer bed frames and safer beds with adjustable heights even to as low as six inches off the floor - otherwise known as low beds, other gizmos securing bed-cracks, and non-skid floor cushions or room mats. Nelson and associates (2004) aptly asserted that these new inventions though they might be fall-proof and enhance safe practice environment, yet could unintentionally also cause "high-risk, high-volume, and high cost adverse events" (p. 649). For the system already at risk for falls, the presence of these additional external physical environmental stressors could make it extremely vulnerable for the normal line of defense to resist.

Aizen, Shugaev, and Lenger (2007) conducted a two-group study in a rehabilitation facility set in Israel for six-months about fall hazards, circumstances, and incidence of falls among consecutively enrolled patients. Findings showed that those participants who used ambulatory equipment such as wheelchairs in conjunction with a fall-risk activity were identified as fall predictors among hospitalized neurologically impaired participants, as well as among those who were prescribed rehabilitative conditioning from hip surgeries.

Tideiksaar, Feiner, and Maby (1993) used a random, controlled design to measure the effectiveness of bed sensors in 70 hospitalized geriatric patients for nine months as a fall prevention intervention. There were 24 falls during the study. Albeit, the experimental group had fewer number of falls ($N = 35, 5$) as compared to the control group ($N = 35, 12$), the findings failed to reject the null hypothesis. There were several variables of note that could have affected this finding. Utility of bed rails was a significant confounder.

Kwok, Mok, Tong, and Tam (2006) examined the use of bed-chair sensor as an alternative to restraints in a stroke rehabilitation hospital set in Hongkong, using a randomized two group design with180 participants in ten months. There were 90 participants in the experimental group, but only 50 participants received the use of bed-chair sensors. Other fall prevention approaches that were utilized in Kwok group's trial (2006) included placement of fall alert notice in the room, call alert device placed within reach, and heightened staff vigilance. Results showed no association between the use of bed-chair sensor and minimal use of bed restraints, as well as no differential change for high-risk for fall elderly sample.

Tzeng and Yin (2006) conducted a descriptive convenience comparative study of the height of standard hospital beds, height of residential beds, and the employee work height in acute care units in Taiwan and its effect on incidence of falls. Commonly, the hospital bed differed in elevation, dimension, texture, and thickness from the patient's home bed. Proper body mechanics dictated that for work-related bedside functions, and in order to prevent job-related back injuries, clinicians routinely adjusted bed heights according to their individual height preferences. However, after task completion, the bed height was not adjusted back to the original position. The authors found that typical residential bed elevation (bed frame & mattress) was 52.0 cm as compared to the hospital bed adjusted to its lowest position of 51.3 cm. However, the typical bedside nurse who needed to adjust bed elevation to working-height measured 70.7 cm. Findings from this survey had significant clinical implications in that patients or family members might not adjust the hospital bed height according to their preferential heights for safe transfer activities. The authors opined that they might be uncomfortable in adjusting the bed height even when it might be deemed unsafe for them to get in or out of bed. There might even be the feeling of reluctance to manipulate hospital equipments and/or unfamiliarity of the devices themselves. Furthermore, the authors made a comparative measurement of bed elevation in the US and found that residential beds (all inclusive bed frame, box, and mattress) measured 60.9 cm as opposed to hospital bed height of 50.7 cm. The average bedside clinician's working height measured 66.0 cm. Subsequently, there was a marked difference between the employee's working-bed elevation and the hospital bed adjusted to its lowest position that could potentially caused a fall event.

Haines and associates (2004) examined the success of a multi-component fall preventive program that included fall-risk alert card, along with a flyer, physical activity, staff in-service, and use of hip protectors among 626 participants during 45 days of care. Methodology used a prospective, randomized, two-group design set in three geriatric rehabilitation units of an Australian sub-acute hospital. Findings showed substantial difference in the fall rates (Peto log rank test $p = 0.045$). The experimental group *(N = 310)* had 30 % decrease in the number of falls *(N = 105*) versus the control group *(N = 316)* with 149 falls. Those who fell in the experimental group were fewer in proportion *(54 vs. 71)* as compared to the control group *(relative risk 0.78, 95%, CI 0.56 to 1.06*). Albeit, there were a total of four fallers, two fallers a piece from the two groups who sustained broken bones related to their falling, and one participant incurred broken femur from the fall even with intact hip protectors, the 28 % drop *(log rank test p = 0.20)* of fall related injuries in the experimental group compared to the control group was clearly encouraging.

A convenience sampling of 1357 in-patients was recruited and grouped into three fall-risk categories in the Williams group's study (2007). Findings showed eight falls per 1000 BDOC, a significant difference in fall outcomes in comparison with the time they looked at in 2002-2003. There was a dramatic drop of the number of falls from 0.95 to

0.80 *(95% CI for the difference -0.14 to -0.16, $p < 0.001$)*. This study lent tentative credibility in implementing a fall prevention plan in acute care settings.

In the meantime, Hignett & Masud (2006) performed a systematic review of environmental risks and its association to hospital falls. Although, various environmental modalities to reduce falls including patient examination, staff education, use of foot protection, bed sensors, floor, and lighting fixtures were implemented, they found no significant results of the aforementioned devices. Surprisingly, they asserted that even bed rails did not prevent falls but instead caused more traumas. Thus, Hignett and Masud's (2006) report was contrary to other studies that cited advantageous use of environmental modalities against fall occurrences (Fonda, Cook, Sandler, & Bailey, 2006; Wolter & Studenski, 1996).

Situational factors. There is another type of environmental stressor identified as situational risk factor (Aizen, Shugaev, & Lenger, 2007; Donoghue, Graham, Gibbs, & Mitten-Lewis, 2003; The Merck Manual of Geriatrics, 2005). Situational risk factors were defined as "certain activities or decisions may increase the risk of falls and fall-related injuries" (The Merck Manual of Geriatrics, 2005, p. 1). For example, wearing inappropriate footwear such as high-heeled shoes or poor illumination, and unsafe behaviors such as inattention to surroundings, or being in haste. Work milieu, social interactions, and relationships might also fall under this category. For example, hospital staff and visitors might influence the environmental conditions where the patient was confined. Even the existing culture within the hospital setting might influence fall events such as teamwork or a "blame ethos" when adverse events occur. Large hospitals with magnet distinctions or small rural facilities might affect the over-all extrinsic feel of the patient surroundings. Even method of payment – private insurance or public hospital utilization might alter the patient's physical milieu by the number and expertise of staff employed. In particular, the level of nursing education and quality of fall training of personnel could also affect the number of falls prevented.

Selected Experimental Studies on Fall Prevention Programs

It had been reported that 30-50 % reduction of falls and fall-related trauma could result when beneficial fall prevention strategies were instituted (AAPMR, 2008). The ninth goal of The Joint Commission's environmental intervention addresses safety features such as patient orientation to hospital surroundings, appropriate lighting and noise reduction, call alarms, as well as reachable and available grab rails. Other fall safety protocols might involve zealous staff surveillance of high risk for fall patients, moving and monitoring patients in proximity to the nursing station, plus personnel training regarding fall prevention strategies. Besides the use of colorful fall badges on patient arms or wrists, identifying them as high-risk for fall, as well as positioning them prominently and strategically close to the nursing station, additional fall preventive approaches included availability and user-friendliness of toileting devices along with alternative measures to restraints.

A study by Von Renteln-Kruse and Krause (2007) examined a prospective cohort trial consisting of 4,272 elderly participants admitted in geriatric hospitals (*mean age 80,* *69 % female*) pre-treatment and 2,982 participants (*mean age 81, 69 % female*) post-treatment. The investigators used a historical control design in the evaluation of a fall reduction protocol in relation to incidence of falls. Multi-treatment protocol comprised of the following; (a) fall-risk evaluation upon admission and post-fall evaluation, (b) use of fall-risk badge/card and brochures, (c) staff assistance during patient mobility, transfer, and during personal hygiene functions, (d) patient and staff fall-education in-service, and (e) instruction of proper use of visual and hearing devices, correct footwear, and ambulatory equipments. Data were analyzed from fall-occurrence reports, functional independence, ambulation measures, incidence of falls and fall-associated trauma, and total number of participants who experienced falls. Baseline fall report was 893 prior to the investigation whereas post-implementation of the treatment showed 468 falls, *(IRR) = 0.82, 95 % CI 0.73 –0.92)*. Baseline fall-injury report was 240 prior to the investigation whereas post-implementation of the treatment showed 129 traumatic falls *(IRR=0.84, 95 % CI 0.67 – 1.04)*. Likewise, findings showed 10 fall-related fractures before treatment as opposed to nine fall-related fractures post-conclusion of study *(IRR=1.40, 95 % CI 0.51–3.85)*. Furthermore, there were 611 patients who fell prior to implementation in contrast to 330 participants who experienced falls after the study. Of note, there was also a significant difference in the fall risk factors *(0.77, 95 % CI 0.68–0.88)*. Yet again, as conducted in acute care institutions numerous interventions clumped together and implemented in toto among the geriatric group showed promise in slashing the number of falls but were less likely effective in mitigating traumatic falls.

Strengthening the functional independent measures along with ambulatory aids might bolster fall-preventive practices in the hospitalized elderly.

The Hofmann group (2003) described a 38 % decline of fall rates and a consequent 50 % decrease in fracture-related injuries from a triad of fall preventive approaches that modified the environmental structure, hospital personnel, and other therapeutic regimen. Significantly, the Chang et al., study (2004) also showed that changing the environment and an exercise activity program had a crucial impact on the incidence of falls. Griffith (2002) reported a fall reduction trial that prescribed various changes in the physical environment that showed profound difference in the fall rates of the experimental group (183 falls, $N = 141$) in comparison to the control group (510 falls, $N = 163$).

In 1998, Mosley and associates conducted an evaluation study of the effectiveness of an evidence-based fall reduction protocol enacted in various units at a Florida VA facility. Findings showed a dramatic 72 % drop in fall rates in 13 units among 21 units that participated. The fall prevention module was designed from state of the science review on falls that was the basis for the fall prevention training course for nurses, in conjunction with a comprehensive patient evaluation. An instrument called "Point by Point: Predicting Elders' Falls" assessment form was utilized to identify in-patients at high risk for falls with a score of 10 or greater from which a broad set of fall preventive procedures were implemented. The regimen included the following fall prevention interventions such as: (a) risk-for-fall signs placed on the patient's wrist, on the chart, bed, and nursing Kardex, (b) green marker on the door indicating a hospital fall incident, (c) comprehensive pharmacological evaluation, (d) mobility and activity review, (e) intensive patient instruction on safe positioning and ambulation, such as gradual orthostatic changes from supine to standing up, (f) asking for help during toileting activities, and (g) milieu orientation.

A major component to the Mosley group's (1998) fall prevention plan was a "safe practice environment" model that was enacted for the patient in or out of bed. Safety features for bedridden patients included; (a) low-bed positioning, (b) split bed rails with only the head-part up, (c) functioning and handy call-button, d) night light, (e) regularly timed toileting assistance, and (f) close surveillance of disoriented patients within sight of the staff at all times. Similarly, rituals for those ambulatory patients to pre-empt falls included: (a) patient admonitions to change positions gradually, (b) asking for support when using assistive devices, (c) "buddy" call-in system, (d) moving patients adjacent to the staff area, (e) appropriate non-slip footwear, (f) clutter-free patient environs, (g) bedside sitting by family or friends, (h) fall-poster in the room, and (i) drug therapy evaluative report. Retrospectively, the patient's chart and fall incident forms were appraised. In addition, risk factors, contributing factors, and circumstances of the fall event were examined. Findings showed 16 fall events. The fallers were assessed as high-risk for falls with prior history of falls. Generally, bedside falls and in bathrooms occurred most frequently when the patient was walking alone and unassisted, climbing over the sidebars, and slipping out of bed at naptime. There was significant difference

($p < 0.003$) in the fall rate pre-fall prevention implementation ($O = 7.07$, $SD = 1.7$) and the post-implementation of the program ($O = 6.33$, $SD = 1.731$).

Interestingly, upon continuance of the fall prevention regimen six months after the conclusion of the study, the hospital tracked further 35 % fall reduction. Remarkably, analysis of the fall occurrences revealed a significant number of environmental hazards that enhanced falls. For example, ambulatory devices such as wheelchairs were not properly secured during transfer activities, and patients declining to call for help when arising from bed, or after toileting. Prescribed footwear was not properly worn. Grab bars in the bathroom were absent or mislaid. Bedside areas become cramped with ambulatory equipments such as wheelchairs, walkers, and crutches, along with other room furniture including bedside tables, geri-chairs, and bedside commodes. Moreover, night-lights were turned off, and call devices were disconnected and/or dropped on the floor. Meanwhile, other fall preventive methods augured poor outcomes as well. The "buddy" system was not effective when the roommate was asleep, or when the roommate acted as aide for the patient in moving the bedrails down. Furthermore, the fall-alert signs and green dots either disappeared, became soiled, or accidentally stripped off the chart, door, or from the patient's arm.

Selected Meta-Analyses on Fall Prevention Trials

Three systematic reviews by Coussement et al., (2008), Oliver et al., (2007) and Chang et al., (2004) are included in this chapter to show the remarkable diversity and magnitude of scientific studies on fall incidence and fall prevention in multiple acute-care and long-term acute care (LTAC) settings. Coussement and colleagues (2008) wrote a scientific paper that examined and analyzed the features, attributes, and merits of fall reduction protocols implemented in acute care and chronic care facilities after meticulous and methodical exploration of five immense databases. The authors set forth 10 inclusion criteria from their review of eight studies, including prospective RCTs that examined various fall prevention practices in acute and long-term care settings from five weeks to 18 months BDOC. A summary of the Coussement group's (2008) meta-analysis can be found in Table 2 of Appendix B.

The Oliver group (2007) conducted a meta-analysis of incidence of falls and fall reduction methods, as well as fall-related fractures among patients in both acute care in hospitals and residential homes (see Table 3 in Appendix B). In addition, the investigators examined the effect of neurological disease related to falls and fall-related fractures. Inclusion criteria for the group's review included type of treatment and health care placement, either hospitals or nursing homes. In hospitals, the fall prevention strategies included a fall-sensor system, a drug list evaluation, environmental modifications, and non-restraint use. The research team examined 26 treatment groups extracted from 22 trials that involved participants who fell one or more times. Thirteen studies that tested multifactorial treatment in acute care settings showed *0.82, 95 %, CI 0.68-0.997* fall rate but no difference in the number of participants who experienced falls nor fall- related broken bones.

Notably, Oliver et al., (2007) rated the Haines' study (2004), the Healey's study (2004), and the Fonda's study (2006) with very high methodological quality showing significant meta-analysis of 18 % decline in fall rates. A key finding from the Oliver group's study (2004) showed that patient examination for fall risk factors and a multi-layered fall-prevention agenda were most beneficial in treating fall predictors *(0.82, 0.72 to 0.94, number needed to treat 11)* and reducing the fall rate per month *(0.63, 0.49 to 0.83; 11.8 fewer falls in the experimental group per 100 participants).* Thus, Oliver and associates (2007) concluded that their meta-analysis showed that a multifactorial fall prevention program caused a "modest effect on falls" (p. 5).

Chang and associates (2004) also conducted a systematic review and meta-analysis of nine RCTs that tested the usefulness of fall prevention approaches relevant to environmental modifications in the community setting among the older population (see Table 4 in Appendix B). The authors extracted fall prevention studies in community settings that measured multiple interventions which were; (a) fall-risk patient examination and appropriate handling, (b) physical activity, (c) environmental changes, and (d) patient and staff fall-prevention training. Findings from random effects analysis conducted by the above investigators, otherwise known as "sensitivity analysis" (p. 2) merging the studies with risk ratio (RR) testing showed a drop in falling hazards *(RR 0.88, 95 % CI 0.82 to 0.95).* However, when studies were coalesced with incidence rate ratio (IRR), data showed lower fall rate per month *(IRR 0.80, 0.72 to* 0.88). Meta-regression was used to measure the effect of individual interventions.

Over-all evaluation of the three meta-analyses above shows that a composite program of multiple fall-prevention and environmental approaches targeting fall risk factors might yet be effective in cutting down the number of falls and the percentage of patients who experienced falls. Coussement (2007), Oliver (2004) and Chang (2004) extracted and analyzed four similar trials that were conducted by Haines (2004), Healey (2004), Mayo (1994), and Vassallo (2004). Coussement (2007) focused more on RCTs and on various environmental interventions in acute care settings, whereas Oliver (2004) reviewed studies with multidimensional fall prevention elements in hospitals, and Chang (2004) focused on multifactorial interventions in the community setting. A major nursing implication then pointed to the fact that environmental modifications were crucial in mitigating falls in various settings as exemplified from the selected meta-analyses.

Conclusions

Trials that examined multi-factorial fall prevention modalities have shown promising results in various settings (Chang et al., 2004; Oliver, Hopper & Seed, 2000). However, little is known about a specialized fall prevention room equipped to prevent falls. While there were numerous studies that investigated community dwellings that implemented environmental remedies for fall prevention (Clemson et al., 2004), there was a dearth of literature about the effectiveness of FPRs in reducing the number of falls in the hospitalized elderly. Moreover, even for randomized controlled trials (RCTs) testing multifactorial fall interventions, which were considered as *gold standards* for clinical studies, it is unclear which one intervention independent of the others had really made the difference in the incidence of falls, and which variable had not. Research exploring fall risk factors in the elderly patients admitted in hospitals has been inconsistent (Lee & Kim, 1997), albeit other risk factors such as prior history of falls had been supported in multiple investigations (Clemson, Cumming, & Heard, 2003; Fonda et al., 2006; Tsai, Witte, Radunzel, & Keller, 1998). In fact, the American Geriatric Society (2001), Morse (1997), and Rubenstein group (2001) have cited that the principal predictor for in-patient falls was a past history of accidental falls. Similarly, Perell and associates (2001) have examined 10 trials relating to previous fall history that readily contributed to subsequent fall occurrences.

Remarkably, Huda and Wise (1998) have also documented inconsistent and non-compliant implementation of fall prevention approaches by hospital staff. Due to the fact that most conventional fall prevention protocols were mostly time-consuming in their methodologies and implementations (McFarlane-Kolb, 2004; Safety and Quality Council, 2005), the feasibility of FPRs where most evidence-based environmental devices and equipments, such as: (a) electrical beds lowered to within six inches off the floor, (b) non-slip mats, (c) bed sensors, (d) hipsters, (e) quick-drying nonskid slippers, and (f) non-skid shower mats, among others, were placed and installed collectively altogether in one specific structural area might actually reduce the number of falls in the hospitalized elderly had not been previously investigated. A causal relationship between FPR, a specific environmental prescription to reduce the number of falls in acute settings amongst elderly high-risk for fall patients has not been identified in the literature. Thus, the gap in knowledge that this study examined was; how specialized fall prevention rooms affected the number of falls among elderly patients admitted in a medical-surgical unit at a VA hospital?

CHAPTER III

PROCEDURE FOR COLLECTION AND TREATMENT OF DATA

For this study, a two-group prospective, experimental-controlled design, using block randomization, was utilized to evaluate the effectiveness of a FPR in reducing falls in the hospitalized elderly during a seven-day hospital stay. This design was used to control for threats to internal validity. The research variables were the FPR and the incidence of falls. The FPR was used as the intervention, duly designated as the independent variable to prevent the number of falls, which was in turn, identified as the dependent variable.

Setting

A large VA hospital with a 350-bed capacity located in the Southwest U. S. metropolis provided the study setting. The investigator equipped eight rooms and bathrooms with specialized safety equipment and devices that were used for the intervention group. These were designated as FPRs. Another eight rooms containing standard equipment were used for the control group that was designated as regular rooms (RRs). Two of the rooms in each group were private rooms containing one bed and six of the rooms in each group were semi private rooms containing two beds.

The FPRs were equipped with low position beds, bed alarms, commode (at side of bed – supplementing urinal) if required, non-skid double-sided socks, non-skid slippers, quick-drying non-skid shower slippers, hipsters, suitable lighting (room illumination at all times), bed trapeze, fall prevention poster, non-exit side rails (raised for support), exit side rail up for support and foot rail down at all times, beveled edged floor cushions/mats, and non-skid shower mats (see Appendix C). The RRs had the usual set-up and structure of a regular hospital room but without the beveled non-skid floor cushion, non-skid shower mat, bed alarm, non-skid slippers, and quick-drying non-skid shower slippers, and hipsters. The patients assigned to the RRs were not issued bed alarms, beveled non-skid floor cushions, non-skid regular slippers, quick-drying non-skid shower slippers, nor hipsters, although the patients were given two-sided non-skid pair of socks and fall-bracelet as required by usual hospital fall prevention protocol.

Population and Sample

The study population was hospitalized elderly male or female patients who were military veterans admitted to a VA hospital in the Southwest region of the United States. The study participants were recruited upon admission through use of randomly generated room assignments concealed inside an envelope prepared by a different team member.

The study sample consisted of 64 conveniently selected patients age 50 and older and screened as high risk for falling (greater than 45 on the MFS). Sample size determination was conducted in consultation with the University statistician. Sample size was determined using a population estimation, and employing differential proportions SamplePower software (Borenstein, 2000) for a power of .80 and alpha of .05, and a large effect size. Effect size was estimated using results from a previous pilot study conducted by the primary investigator (PI). A five percent attrition rate was built in.

A random computer generated room assignment contained in a sealed envelope was used to randomize eligible subjects who voluntarily consented to participate in the study in blocks of sixteen. The PI was blinded to the random room assignment contained inside the sealed envelopes. The randomization in blocks of sixteen was done so that for every sixteen patients randomized, eight participants were assigned to the FPRs and an equal number assigned to the RRs. Thus, the design was balanced with 32 in the experimental group (assigned to FPR beds) and 32 in the control group (assigned to RR beds).

The sample was recruited from a medical-surgical acute care unit. Ninety percent of all patients admitted to the 25-bed study unit were at high risk for falls (greater than 45 on the MFS). This generated a sufficient number of patients for randomized block sampling. On average the unit maintained a 98 % occupancy rate and length of stay varied from 10 to 42 bed days of care (BDOC). The inclusion criteria for the study population were: (a) age 50 and older, (b) patients with a score of 45 and greater on the MFS, (c) English speaking, (d) admitted in-patients with hospital stay of a minimum of seven days, (e) patients who consented verbally and in written form to participate in the study, and (f) patients admitted in the unit setting that met study eligibility albeit, with various medical-surgical diagnoses, and in varying degrees of rehabilitation. The exclusion criteria were (a) patients with known cognitive impairments or mental health problems that would significantly impair their ability to respond to the questions and adhere to instructions, and (b) patients who might have consented initially but could refuse to be followed-up for the seven-day duration of the study.

Protection of Human Subjects

Applications were submitted and were duly approved by the Institutional Review Boards (IRB) at Baylor College of Medicine (BCM) (see Appendix D), Michael E. DeBakey Veterans Affairs Medical Center (MEDVAMC) (see Appendix D), and Texas Woman's University (TWU) in Houston (exempt review) prior to beginning of data collection (see Appendix D). Participants were given complete and informed written and verbal consent prior to participation (see Appendix F). Confidentiality and anonymity were maintained using a coding system and all study materials and documents were protected in a locked cabinet within a secure office.

Risks of the study included participant fatigue or discomfort during time of follow-up interview for a seven-day duration. Benefits of the study included personal knowledge of the patient's risk for falling, information about strategies for fall prevention, and additional attention given by the principal investigator during follow-up.

Instruments

Several instruments were used for this study. The MFS screened patients for their propensity for falling. The DDF was used to collect personal data such as age, race, or medical diagnosis. The ESC was used to ensure that safety devices and equipments were present in the FPRs. The HFIRF was used as a written document of a fall occurrence during the seven-day hospitalization. The patient's subjective report of fall was also used to corroborate and/or report a fall event during the seven-day duration of hospital stay.

Morse Fall Scale (MFS)

The MFS was used as the high risk for fall screening instrument in this study. This scale screened patients who were imperiled for falling and consisted of six items that were then scored independently from zero to 30 (see Appendix E). It rated three levels of fall risks with corresponding nursing interventions. The cutoff score for this study was 45 and greater to designate the greater likelihood for hospital falls. The high risk for fall level required primary prevention nursing interventions (Morse, 1997). A recent study conducted in Hongkong by Chow and associates (2007) evaluated the MFS utility in examining the fall-risk of hospitalized Chinese patients. The investigators performed reliability tests on internal consistency, item analysis, inter-rater, and test-retest reliability of the MFS using a cross-sectional design in three rehabilitation hospitals among 954 conveniently sampled medical and geriatric patients. Chow and associates (2007) found that discriminative validity measurements of the MFS were 31 % sensitivity and 83 % specificity when the score was based on a cutoff point of 45. Inter-rater reliability showed an excellent ICC value of 0.97 (*95 %, CI 0.94-0.98*) as well as a commendable repeatability of ICC value of 0.98 (*95 %, CI 0.98-0.99*). The elevated inter-rater reliability *(r = 0.97)* of the MFS implied that the instrument was effortless and uncomplicated for the users to apply and utilize in the clinical setting. Thus, the MFS was considered reliable in terms of stability and consistency. However, item analysis showed minimal reliability index by the Cronbach's *alpha coefficient* (*0.26*), with a low to moderate correlation of the various items (Chow et al., 2007). Meanwhile, Morse, Morse, and Tylko (1989) cited the following discriminative validity scores of the MFS, which were; 72 % sensitivity and 51 % specificity. Other validity scores reported were; 51 % accuracy, 38 % positive predictive value, 81 % negative predictive value, and 30 % prevalence (Morse, Morse, & Tylko, 1989). Other quantitative scores reported were 82.9 % effortless utility and 54 % rapid scoring at approximately 120 seconds (Morse, Morse, & Tylko, 1989). The inter-rater reliability and discriminate analysis were found to be satisfactory in the validation of the instrument. According to Morse (1997), measurement of the inter-rater reliability of the six-item scale was 0.96 and testing was able to accurately classify 78 % of the experimental group and 83 % of the control group. However, the value of the *alpha coefficient* in Morse's initial study was low at *0.16* (Morse, Morse & Tylko, 1989).

Demographic Data Form (DDF)

The DDF was used to record age, race, gender, admission and discharge dates, hospital stay, medical/surgical diagnosis, MFS score, assistive devices used, and participant's code number (see Appendix A2).

Equipment Safety Checklist (ESC)

The ESC was used to measure the FPR. It contained 10 major classifications of domains under which were listed various environmental hospital paraphernalia. The total score was 51. The ESC score was calculated by adding all the items checked once daily by the PI. The possible range of score is 0-51, with 51 indicating the highest possible score. Not all of the equipments were present if the patient did not require or need a particular device (i. e., IV pole because no IV medications or solutions were ordered). There had not been any published reliability or validity conducted in regards to the ESC to date as this tool had only been primarily used as a checklist. The ESC was adapted from the *Fall Prevention Module* (2001) used by the U.S. Department of VA Hospital in Tampa, Florida. However, two experts involved in extensive fall studies at the commencement of the study reviewed content validity of the ESC.

Hospital Fall Incident Report Form (HFIRF)

The HFIRF (see Appendix A3) was objectively reviewed to calculate actual fall incidents as witnessed and recorded by the staff. It described the circumstances of the fall incident and other demographic data. This form was completed each time a patient fell during his or her hospitalization. It contained a number of questions designed to uncover circumstances, conditions, and characteristics of each situation associated with the fall events. Information about the patient's diagnosis, demographics, medications in the previous 24 hours, extent of injury, and other circumstances surrounding the fall were recorded. Moreover, the staff that completed the form was asked to state an opinion on whether the fall could have been prevented and how it could have been prevented.

Data Collection

Upon admission, the patient was evaluated for fall risk by the admitting staff using the MFS. Patients who scored 45 and greater were considered high-risk for falls.

The PI then requested verbal and written consents for study participation from the eligible patient. Afterwards, a sealed envelope with a randomly placed room assignment was opened by any staff in the unit, and only then would the eligible subject be randomly assigned either to either the experimental group to be placed in an available FPR bed, or to the control group to be assigned in an available RR bed. The control group received usual care for fall prevention. All participants received verbal and written instruction on fall prevention upon arrival to the unit, which was the standard of care. Block randomization of patients was contingent upon the availability of beds in the FPR. Thus, when all the eight FPR beds were occupied, enrollment in both the control and experimental groups was temporarily stopped, until a FPR bed then became available. Data collection was performed from June to September 2008.

Participant Enrollment and Assignment

A convenience sample of 120 enrollees who were admitted in the study unit and met eligibility criteria were verbally requested to participate in the study. Of the 120 participants, nine patients *(9 %)* declined participation, and 47 *(42 %)* did not stay the requisite seven-day follow-up for various reasons for both groups. Of the 47 who failed seven-day retention, 19 *(40 %)* were assigned in the experimental group and 28 *(60 %)* were assigned to the control group. Patients who did not meet retention criterion of seven-day hospitalization included those participants who were transferred to critical care or other units *(n = 2; 4 %)*, died *(n = 1; 2 %)*, had emergent surgery *(n = 1; 2 %)*, or discharged home in less than a week *(n = 43; 91 %)*. Sixty-four participants *(58 %)*

consented both in verbal and written consents, stayed for seven days, and, thus were analyzed. There was equal number of participants in the control *(n = 32; 50 %)* and experimental groups *(n = 32; 50 %)*. Those who were discharged earlier than the requisite follow-up of seven-day hospitalization for both groups happened during, second *(n = 6; 13 %)*, third *(n = 9; 19 %)*, fourth *(n = 9; 19 %)*, fifth *(n = 13; 28 %)*, and sixth *(n = 10; 21 %)* days respectively of follow-up assessment. Forty-seven participants did not meet retention criterion for an attrition rate of 42 %. These participants were then excluded from data analysis. Specific enrollment breakdown is presented in Figure 2.

Study Participant Algorithm

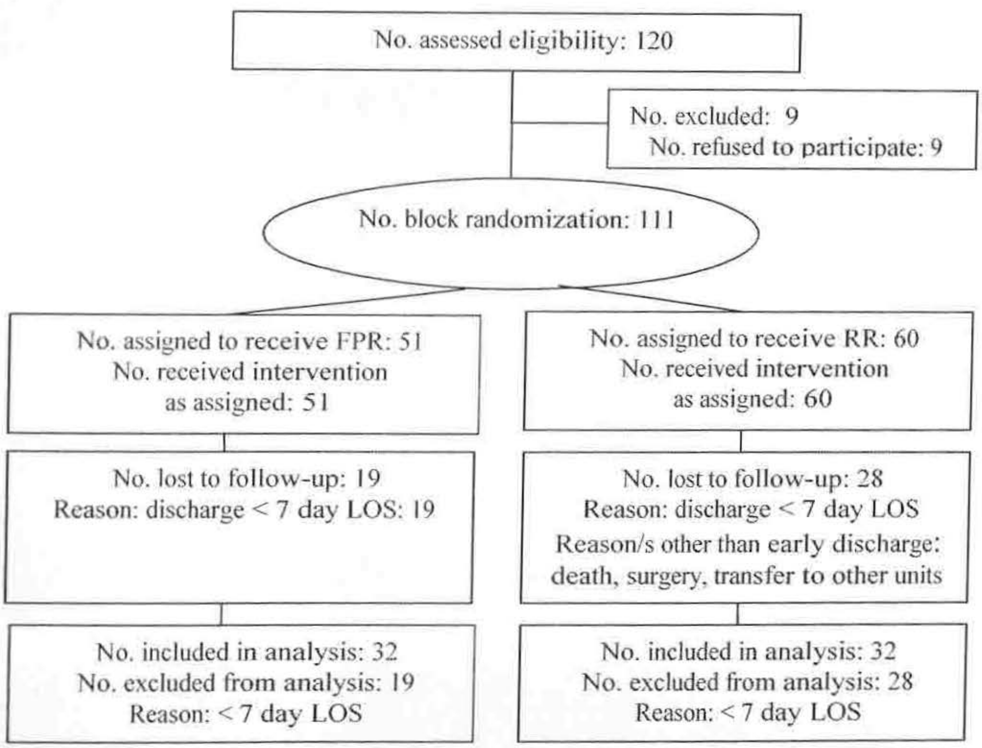

Figure 2. Profile of Randomized Controlled Study Participants

Treatment of Data

The software SPSS version 15.0 was utilized for data management and analysis. Descriptive statistics appropriate for the level of measurement was conducted. The demographic data that included age, gender, and ethnicity of participants were analyzed by means and standard deviations. Fisher's Exact Probability Test analyzed the number of fallers and nonfallers between the control and experimental groups.

Pilot Study

A randomized controlled pilot study tested the effectiveness of an environmental primary prevention intervention in the form of FPR among 30 subjects assessed as high-risk for falls (score 45 and greater on the MFS), aged 50 and over and admitted to a large VA hospital located in the Southwest U.S. metropolis. A two-group prospective, four block-randomized design using concealed assignment to FPR with a fourteen-day follow-up assessment was used. Daily follow-up visits for the fourteen day length of stay (LOS) were performed by the PI to check the integrity of the FPR.

Out of 30 randomly-assigned subjects, 29 were analyzed. One participant was discharged earlier than the requisite fourteen-day LOS, and thus, was not included. A Fisher's Exact Probability Test comparing fallers and non-fallers and FPR versus routine care groups was conducted. While the result showed no significant statistical difference (two-tail = p *0.168*), the clinical significance of fallers, assigned to regular care, *13.7 %* ($n = 4$) versus a faller assigned to FPR *3.4 %*, ($n = 1$) might be more meaningful. The lack of significant results was likely due to the small sample size used in the pilot.

CHAPTER IV

ANALYSIS OF DATA

The purpose of this randomized controlled study was to test the effectiveness of an environmental primary prevention intervention in the form of FPR for older hospitalized patients at high risk for falling. One hundred twenty eligible participants were conveniently recruited to participate in the study. A total of 111 *(93 %)* participants gave verbal and written consents. Nine participants *(7 %)* declined participation. All participants were randomly assigned to either a standard hospital room or FPR. Fall status was gathered through the Hospital Fall Incident Report Form (HFIRF) and self-reports. At the seven-day follow-up period, 64 participants remained for a 58 % retention rate. Of the 47 who did not complete the seven-day hospitalization, 44 participants were discharged before completion of the seven-day follow-up period; two were transferred to other units, and one died. Twenty-eight of the dropped participants were in the control group and 19 were in the experimental group (see Table 5). The demographics and diagnoses of the 47 excluded participants were not significantly different from those participants retained for the study sample. Both groups were predominately male and white with a mean age of 64 years. This chapter includes a description of the sample and reports the study findings.

Table 5

Dropped Participants Length of Stay by Treatment Group

Length of Stay	Experimental Group		Control Group		Total	
Number of Days	n	%	n	%	n	%
2	2	4 %	4	9 %	6	13 %
3	3	6 %	6	13 %	9	19 %
4	0	0 %	9	19 %	9	19 %
5	6	13 %	7	15 %	13	28 %
6	8	17 %	2	4 %	10	21 %
Total	19	40 %	28	60 %	47	100 %

Description of the Sample

Sample Description

Sixty-four participants who met eligibility criteria and completed the seven-day follow-up were used for the final analysis. The two groups were evenly matched with 32 participants in each group. Sample frequencies of the study variables of both groups are presented in Table 4. The majority of the participants were white males, 60-69 years of age. There were two females in the control group only and both groups had a matching identical racial ethnicities (see Table 6). The mean age of the experimental group participants was 64 *(SD 9.13)* which was a year younger than the control group *mean of 65 (SD 8.38)*. The participants were diagnosed with 41 different medical and surgical conditions, of which knee and hip arthroplasties and stroke were the most predominant.

Two or less participants were reported in seven of the diagnosis categories (Appendix G). The majority of the participants were ambulatory and most were prescribed rehabilitative therapy. The majority of participants used assistive devices, such as manual wheelchairs electric scooters and Rollator walkers. There were a total of four fallers in the sample.

Table 6

Sample Frequencies: Age, Gender, Race, Hospital Stay & Fall Status (N = 64)

Variable	Experimental Group (n = 32)		Control Group (n = 32)		Total Frequencies (N = 64)	
	n	%	n	%	n	%
Gender						
Male	32	50 %	30	47 %	62	97 %
Female	0	0 %	2	3 %	2	3 %
Race						
White	18	28 %	18	28 %	36	56 %
Black	12	19 %	12	19 %	24	38 %
Hispanic	2	3 %	2	3 %	4	6 %
Age Mean(SD)	64	(9.13)	65	(8.38)	64.39	(8.94)
50-59	12	19 %	6	9 %	18	28 %
60-69	9	14 %	19	30 %	28	44 %
70-79	10	16 %	4	6 %	14	22 %
80 and over	1	1 %	3	5 %	4	6 %

Table 6 *(continued)*.

Diagnosis						
Knee Arthroplasty	8	13%	6	9 %	14	22 %
Hip Arthroplasty	5	8 %	3	5 %	8	13 %
Stroke	6	9 %	5	8 %	11	17 %
Osteoarthritis	1	1 %	2	3 %	3	5 %
All others	12	19 %	16	25 %	28	43 %
Fall Status						
Fallers	1	2 %	3	5 %	4	6 %
Non-Fallers	31	48 %	29	45 %	60	94 %
Assistive Devices						
Wheelchairs	20	31 %	14	22 %	34	53 %
Scooters	1	2 %	6	9 %	7	11 %
Walkers	12	19 %	11	17 %	23	36 %

Profile of the Fallers and Circumstances of Fall

There were three fallers in the control group and one faller in the experimental group (see Table 7). All of the fallers sustained negligible injuries.

The first faller in the control group was male, white, 76 years old, and was diagnosed with rectal hemorrhage. He scored 95 on the MSF and fell at 6:00 a.m. on the second day of admission while getting out of bed to go to the bathroom. The fall was reported in the Hospital Fall Incident Report Form (HFIRF), and subsequently validated by patient's self-report. The second faller was also male, white, 55 years old, and was diagnosed with alcohol abuse. He scored 55 on the MSF and fell at 9:00 a.m. on the third day of admission while attempting to transfer from chair to bed. The fall was documented in the HFIRF and subsequently validated by patient's self-report. The third and final faller in the control group was male, 65 years old, Hispanic, and was diagnosed with neuro-syphilis. He scored 50 on the MSF and fell at 2:00 p.m. while he was getting out of bed to ambulate. The fall was reported by the patient. The staff failed to write up the reported fall event and no HFIRF generated.

The lone faller from the experimental group was male, white, 77 years old, and had a left total knee arthroplasty. He scored 50 on the MFS and fell at 10:00 p.m. on the fourth day of admission while attempting to transfer from bed to wheelchair without assistance. The fall was documented in the HFIRF and subsequently validated by patient's self-report.

Table 7

Demographic Characteristics of Fallers: Profile of Fallers and Circumstances of Falls (n = 4)

Faller	Group	Age	Sex	Race	MSF Score	Fall Day and Time	Place of Fall	ADL at Time of Fall	Medical Diagnosis	Report
1	E	77	M	W	50	Fourth day 10 pm	Bedside	Transfer from bed to chair	S/P left total knee arthroplasty	HFIRF
2	C	76	M	W	95	Second day 6 am	Bedside	Getting OOB to bathroom	Rectal bleed	HFIRF
3	C	61	M	W	55	Third day 9 am	Bedside	Transfer from chair bed	Alcohol abuse	HFIRF
4	C	65	M	H	50	Seventh day 2 pm	Bedside	Getting OOB to Walk	Neuro-syphillis	Self-report

Key: C = Control; E = Experimental; OOB = Out of bed; HFIRF = Hospital Fall Incident Report Form

Comparison of Fall Rates: Sample, Setting, and Hospital during Data Collection Period

The data collection period for this study transpired from June to September, 2008. During that time, the institution generated two quarterly fall rate reports that were broken down by service. The study unit contained two specialized services; neurology and rehabilitation respectively. The overall two-quarter fall rate was 3 % for the institution, 6 % for the combined unit, and 6 % for the study participants (see Table 8).

Table 8

Third and Fourth Quarters (2008) Fall Rates by Institution, Specialty Services, and Study Group Assignment

Fall rates (3rd & 4th quarters 2008)	Frequencies	
	f	%
Institution *(BDOC = 7,200)	216	3.0 %
Specialty service (combined N = 384)	23	6.0 %
Neurology (n = 200)	10	5.0 %
Rehabilitation (n = 184)	13	7.1 %
Study (N = 64)	4	6.3 %
Experimental group (n = 32)	1	3.1 %
Control group (n = 32)	3	9.4 %

*BDOC = Bed Days of Care

Findings

Research Hypothesis

This randomized controlled study tested the effectiveness of an environmental primary prevention intervention in the form of FPR among high-risk for falls elderly patients in the hospital and addressed the following research hypothesis: Hospitalized patients, aged 50 or older who scored 45 and greater on the MFS would report lower falls during a seven-day hospital stay when assigned to FPRs than comparable hospitalized patients assigned to standard rooms.

A one-tailed Fisher's Exact Test was conducted on the 64 participants to assess whether the proportion of fallers was less in the experimental group than in the control group (see Table 9). This statistical test was used because the expected frequency count in two of the four cells was less than five. Test results were not significant, *($p = 0.306$).* Thus, the null hypothesis was retained and there were no significant differences between the participants assigned to the FPRs and those placed in the RRs.

Table 9

Fisher's Exact Test between Fallers & NonFallers in Two-Group Design (N = 64)

Sample	Experimental Group (n = 32)	Control Group (n = 32)
Fallers	1	3
Non-Fallers	31	29
Total	32	32
Fisher's Exact Test		$p = 0.306$

Summary of the Findings

This randomized two-group study examined the effectiveness of FPRs among 111 hospitalized patients, aged 50 or older who were admitted in a combined neurology and rehabilitation units, and who scored 45 and greater on the MSF. Sixty four participants met all eligibility criteria and were analyzed. In this predominantly white male group, most participants were 60-69 years of age with some type of medical and surgical diagnoses. There were four fallers, three in the control group and one in the treatment group. There was no statistical significance between the two groups as measured by one-tailed Fisher's Exact test. Therefore, the study hypothesis was not supported.

CHAPTER V

SUMMARY OF THE STUDY

This randomized controlled study tested the effectiveness of an environmental primary fall prevention intervention in older hospitalized patients at risk for falling. This chapter summarizes the study with discussion of findings, conclusions, implications for nursing practice, and recommendations for further study.

Discussion of Findings

The Neuman System's Model (NSM) was used as a theoretical framework to examine the effectiveness of a fall prevention room (FPR) as a primary prevention intervention in mitigating falls. The FPR tested in this study was designed as a primary prevention intervention and was designed to strengthen the system's flexible lines of defense and prevent falls and fall related injuries. While the participants who used the FPR did have fewer falls than those in a conventional environment, the difference was not significant.

These study results run contrary to the major bulk of the cited literature, which reported that fall incidents, could be substantially lowered by initiating and implementing various modalities for fall reduction. Use of fall preventive devices and equipment that included low beds, bed alarms, hipsters, non-skid socks, non-skid slippers, non-skid shower mat, quick-drying slippers, non-skid floor cushion were all reported to lower fall rates (Chang et al., 2004; Haines, Bennel, Osborne, & Hill, 2004). These devices were very similar to the devices and equipment used in the FPR. Quigley et al. (2009) reported that the use of protective bundles such as hip protectors, bedside floor mats, and adjustable-height beds in a VA hospital decreased the number of falls and fall-related injuries on two medical-surgical units.

Environmental modifications similar to the ones instituted in this study were found to be effective in studies by Zimring and Ulrich (2004), and Halfon, Eggli, Van Melle, and Vagnair (2001) and the Hathaway group (2001). Halfon et al. (2001) reported that 32 % of the slips reported could have been forestalled with use of non-skid footwear. In this study, all the participants were issued protective footwear such as non-skid socks following hospital protocol. In addition, those participants assigned to the FPR were provided with quick-drying shower slippers and non-skid regular slippers.

In this study, those assigned in the FPR had non-skid bathroom floor mats. Fonda and associates (2006) reported that extrinsic environmental modifications that included non-slip toilet floor, showed 19 % less falls per 1,000 BDOC (12.5 v 10.1, p 0.001) and a consequential impressive 77 % reduction of fall-related injury rate during the study period. The same study also found that bed sensors and low beds, decreased fall rates. In this study, the participants assigned to the FPR had additional equipment installed including low beds and bed alarms.

A number of factors might have played a role in the results. Fall prevention measures were dictated by hospital protocol and availability of medical devices and appliances. In particular, the number of pieces of equipment was not homogenous because the study setting dictated the regimen prescribed for each individual patient. For example, a patient undergoing IV microbial therapy had use for IV stands, whereas those who were admitted for rehabilitation therapy did not use IV stands. Hospital stay was also problematic. Forty-seven participants who were discharged earlier than the approved seven-day follow-up were not retained in the study though inclusion of these cases would not have influenced results, as none of the 47 early discharges was fallers.

One major factor that could have influenced this finding was the small sample size that completed the requisite seven-day hospitalization. Although 111 were enrolled, only 64 participants were retained and subsequently analyzed. Since the overall fall rate for the study was so small with a total of four falls, it was difficult to discern an appreciable difference in the one fall for the experimental group as opposed to the three falls for the control group. Furthermore, there were a number of environmental protective appointments such as bed controls at fingertips, movable hand rails, and bed trapezes in the regular rooms in accordance to standard hospital protocol. Thus the fact that this study found no differences among fall rates when other studies did is likely due to a small sample size, the small number of fallers, and in the extremely protected external environment encountered within the VA system. The high extent of existing culture of safety within the VA system far surpassed the safety programs compared to civilian hospitals.

Therefore, while no significant differences were found between the FPR and RR, the FPR might yet be further tested as a feasible environmental intervention in mitigating falls by using a larger sample size or in a different environment that did not have as many protective bundles already in place.

Conclusions

The use of a fall prevention room as opposed to a standard patient room as an intervention to reduce falls was not statistically validated. Within the limitations and based on the results of this study the following conclusions were derived:

1. The fall prevention room was not successful in reducing the number of in-patient falls.
2. The characteristics of the fallers mirrored the characteristics of the study sample.
3. The small sample size and the small number of falls affected study outcomes.
4. The fall rate in the study unit was reduced by 3 % for the experimental group compared to the unit fall rate as a whole.

Implications for Nursing Practice

The implications suggested by this study are:

1. Environmental protections such as those generally found in the VA hospital system and specifically incorporated into a fall prevention room serve to keep the fall rates low.
2. Reductions in fall rates by environmental modifications such as FPR have economic benefits that offset the expense of such modifications.
3. Shorter length of hospitalization may be feasible when falls are prevented.

Recommendations for Future Study

The following recommendations are made for further research:

1. Study replication that increases the sample to a minimum of 350 to provide boost power.

2. Study replication that utilizes bed days of care (BDOC) or patient days of hospitalization instead of actual patients for sample.
3. Study replication using other hospital specialty settings, such as orthopedic or psychiatric units, and including older female participants.
4. Future studies to test additional fall prevention personal equipments other than used in this study, such as fall t-shirts, hip shields, lap, vest or shoulder restraints.
5. Future studies to assess other fall-prevention protocols such as use of 24 hour bedside-sitters provided by family/friends or institution, hourly-rounding by staff, or electronic video-recording.

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APPENDIX A

QUESTIONNAIRE PACKET

1. Equipment Safety Checklist (ESC)
2. Demographic Data Form (DDF)
3. Hospital Fall Incident Report Form (HFIRF)

I. EQUIPMENT SAFETY CHECKLIST (ESC)

Equipment Safety Checklist

Wheelchairs	
Brakes	Secures chair when applied
Arm Rest	Detaches easily for transfers
Leg Rest	Adjusts easily
Foot Pedals	Fold easily so that patient may stand
Wheels	Are not bent or warped
Anti-tip Devices	Installed, placed in proper position
Electric Wheelchairs/Scooters	
Speed	Set at lowest setting
Horn	Works properly
Electrical	Wires are not exposed
Beds	
Side Rails	Raise and lower easily
	Secure when up
Wheels	Roll/turn easily, do not stick
Breaks	Secures the bed firmly when applied
Mechanics	Height adjusts easily (if applicable)
Transfer Bars	Sturdy, attached properly
Over-bed Table	Wheels firmly locked
	Positioned on wall-side of bed
IV Poles/Stands	
Pole	Raises/lowers easily
Wheels	Roll easily and turn freely, do not stick
Stand	Stable, does not tip easily (should be five point base)
Footstools	
Legs	Rubber skid protectors on all feet
	Steady – does not rock
Top	Non-skid surface
Call Bells/Lights	
Operational	Outside door light
	Sounds at nursing station
	Room number appears on the monitor
	Intercom
	Room panel signals
Accessible	Accessible in bathroom
	Within reach while patient is in bed
Walkers/Canes	
Secure	Rubber tips in good condition?
	Unit is stable
Commode	
Wheels	Roll/turn easily, do not stick
	Are weighted and not "top heavy" when a patient is sitting on it
Breaks	Secure commode when applied
Geri/Broda Chairs	
Chair	Located on level surface to minimize risk of tipping
Wheels	Roll/Turn easily, do not stick
Breaks	Applied when chair is stationary
	Secure chair firmly when applied
Footplate	Removed when chair is placed in a non-tilt or non-reclined position
	Removed during transfers
Positioning	Chair is positioned in proper amount of tilt to prevent sliding or falling forward
Tray	Secure
Bathroom Non-skid Mat	
Floormat	Secure

2. DEMOGRAPHIC DATA FORM (DDF)

Demographic Data Form Code #______

Name ______________________________ Last 4 _______ Date of Birth __________

Address ______________________________________ Home phone ______________

Additional Contacts Name____________ _______________ Phone ____________

Caregiver [1] Yes Name ________ Relationship: ________ (relative, friend, VNA)

[2] No/none

Participant Demographic Profile Form

Directions: Please fill in or circle the appropriate blanks/variables:

Date: _______ PI initials __________

Randomized to: [1] (Experimental Group ____

[2] Control Group_____

Age: _____ [1] (50-55)

______ [2] (56-60)

______ [3] (61-65)

______ [4] (66-70)

______ [5] (71-75)

______ [6] (76-80)

______ [7] (81-85)

______ [8] (86 –90)

______ [9] 91 and above)

Sex: [1] M _____ [2] F _____

Hospital Stay*: [7 days]*

Admission Date: -----/------/------- (month/day/year)

Discharge Date: -----/------/------- (month/day/year)

Ethnicity: [1] Caucasian/White _____

[2] African-American/Black ____

[3] Hispanic-American ______

[4] Asian-American ______

[5] Indian-Americans ____ (from India)

[6] Native Americans ____ (Indians)

[7] Other

Medical/Surgical Diagnosis:

[1] HTN ____

[2] DM _____

[3] Parkinson's Disease ______

[4] Stroke

[5] Others

Ambulatory: [1] Yes ____

[2] No ____ Why: _______

Assistive Device: [1] Yes ____What_______

[2] No ____

3. Hospital Incident Report Form (HFIRF): page 1

Department of Veterans Affairs

REPORT OF SPECIAL INCIDENT INVOLVING A BENEFICIARY

NOTE: For type of incident to be reported on this form, see Chapter 2, Section A, paragraph 2, DM&S Supplement to VA Manual MP-1, Part I.

1 TO

☐ STAFF PHYSICIAN ☐ OFFICER OF THE DAY ☐ CHIEF, DOMICILIARY OPERATIONS

The following is a report of an incident affecting the beneficiary identified below.

DESCRIPTION OF INCIDENT *(Including use of beneficiary, date of admission, diagnosis and medications)*

DATE AND TIME OF INCIDENT

INCIDENT WAS

☐ WITNESS BY ME

☐ DATE AND TIME REPORTED

☐ REPORTED TO PHYSICIAN

☐ REPORTED TO ME BY *(Give name and title)*

2 TO

☐ CHIEF OF STAFF ☐ CHIEF DOMICILIARY MEDICAL SERVICE ☐ CLINICAL DIRECTOR

DATE AND HOUR BENEFICIARY WAS SEEN BY UNDERSIGNED

REMARKS

DATE	SIGNATURE AND TITLE *(Staff Physician, Officer of the Day, or Chief, Domiciliary Operations)*

BENEFICIARY'S NAME SOCIAL SECURITY NO. WARD NO. NAME OF FACILITY DATE

REPORT OF SPECIAL INCIDENT

INVOLVING A BENEFICIARY

VA FORM 10-2633
FEB 1990

EXISTING STOCK OF VA FORM 10-2633, NOV 1982, WILL BE USED

Hospital Incident Report Form (HFIRF): page 2

3a TO: (NAME) TITLE

PLEASE FURNISH THE FOLLOWING ADDITIONAL INFORMATION AND RETURN THIS FORM

DATE	SIGNATURE AND TITLE *(Chief of Staff, Clinic Director, or Chief, Domiciliary Medical Service)*

3b TO: **Director** ☐ NO FURTHER ACTION INDICATED ☐ INVESTIGATION INDICATED

COMMENTS AND RECOMMENDATIONS

IS THIS INCIDENT REPORTABLE TO VA CENTRAL OFFICE UNDER PROVISIONS OF CHAPTER 2, SECTION A, DM&S SUPPLEMENT MP – 1, PART I?
☐ YES ☐ NO

DATE	SIGNATURE AND TITLE *(Chief of Staff, Clinic Director, or Chief, Domiciliary Medical Service)*

4 TO:

☐ NO FURTHER ACTION REQUIRED

☐ ACTING AS CHAIRPERSON, CONVENE A BOARD OF INVESTIGATION WITH TWO OTHER MEMBERS *(Names shown below)* EXAMINE WITNESSES, AND SUBMIT YOUR REPORT AND RECOMMENDATIONS TO ME BY _____

REMARKS

DATE	SIGNATURE AND TITLE *(Chairperson or investigator)*

5 TO: **Director** Submitted herewith is report with recommendations of the investigation concerning the incident affecting this beneficiary.

REMARKS

DATE	SIGNATURE AND TITLE *(Chairperson or investigator)*

6 TO: **Regional Director (10BA-)** This report and related investigation reports are forwarded with the following comments and recommendations.

COMMENTS AND RECOMMENDATIONS

DATE	SIGNATURE OF DIRECTOR

7 TO: **Director** Your report has been reviewed.

REMARKS

DATE	SIGNATURE AND TITLE

VA FORM FEB 1990 **10-2633**

*U.S. Government Printing Office: 1992 – 282-604/45162

APPENDIX B

LIST OF RANDOMIZED CONTROLLED TRIALS

1. Table 1. Definitions of Fall and Comparisons to this Study
2. Table 2. Coussement's Meta-Analysis: Comparison of Eight Studies by Design, Interventions, Outcome Variables, and Results
3. Table 3. Oliver's Meta-Analysis: Comparison of 13 Studies by Design, Interventions, Outcome Variables, and Results
4. Table 4. Chang's Meta-Analysis: Comparison of Nine Studies by Sample, Design, Interventions, and Results

Table 1

Definitions of Fall and Comparisons to this Study

First Author	Year	Similarities and Differences	Definitions of Fall
Aizen	2007	Similar	''An incident in which a patient suddenly and involuntarily came to rest upon the ground or surface lower than their original station" (p. 3).
Berg	1997	Different	''Losing your balance such that your hands, arms, knees, buttocks or body touch or hit the ground or floor'' (p. 262).
Canadian Institute for Health Information	2002	Similar	''An unintentional change in position where the elder ends up on the floor or ground'' (p. 164).

Table 1 *(continued)*.

Carter	2002	Different	"Inadvertently coming to rest on the ground or other lower level with or without loss of consciousness and other than as the consequence of sudden onset of paralysis, epileptic seizure, excess alcohol intake or overwhelming external force" (p. 999).
Centers for Disease Control (CDC)	2008	Different	"Injury received when a person descends abruptly due to the force of gravity and strikes a surface at the same or lower level" (CDC, 2008).
Kellogg International Work Group	1987	Similar	A fall is an event which results in a person coming to rest inadvertently on the ground or other lower level and other than as a consequence of the following: sustaining a violent blow, loss of consciousness, sudden onset of paralysis, as in a stroke, or an epileptic seizure. (p. 4)

Table 1 *(continued)*.

Lamb	2005	Similar	“An unexpected event in which the participants come to rest on the ground, floor, or lower level’’ (p. 1619).
Lane	1999	Similar	“The experience of hospitalized adults changing posture in a downward direction suddenly and involuntarily” (p. 38).
Means	1996	Similar	‘‘Any involuntarily change from a position of bipedal support (standing, walking, bending, reaching, etc.) to a position of no longer being supported by both feet, accompanied, by (partial or full) contact with the ground or floor’’ (p. 1032).
Tideiksaar	2002	Different	‘‘Any event in which a person inadvertently or intentionally comes to rest on the ground or another lower level such as a chair, toilet or bed’’ (p. 15).
Williams	2007	Similar	“An unplanned descent to the floor by a patient or visitor” (p. 319).

Table 2

Coussement's Meta-Analysis: Comparison of Eight Studies Trials by Design, Interventions, Outcome Variables, & Results

First Author Year	Design	N	Interventions: Type	Interventions: Duration	Patient Outcome Variables: Falls	Patient Outcome Variables: Fallers (%)	Results
Bischoff 2003	RCT	122	Calcium and Vitamin D	12 weeks	(per person/wk) Control: 0.08; Experimental: 0.03	Control: 30.0 Experimental: 22.6	Not significant
Donald 2000	RCT	54	Flooring (carpet vs. vinyl)	9 months	(per person/mo) Control: 0.00 Experimental: 0.04	Control: 03.8 Experimental: 25	Statistically significant
Haines 2004+	RCT	626	Alert card, Hip protector	10 months	(per 100 obd) Control: 1.61 Experimental: 1.12 after 45 days	Control: 22.5 Experimental: 17.4	Statistically significant

Table 2 *(continued)*.

Healey 2004+	RCT	1,654	Environmental review	1 year	(per 100 obd) Control: 1.92 Experimental: 1.3	Not available	Not calculated
Mayo 1994+	RCT	134	ID bracelet	1 year	Not available	Control: 30.4 Experimental: 41.5	Not significant
Schwendimann 2006	CT	409	Environmental review	4 months	(per 100 obd) Control: 1.57 Experimental: 1.15	Control: 11.8 Experimental: 12.6	Not significant
Tideiksaar 1993	RCT	70	Bed alarm system	9 months	(per person/mo) Control: 0.04 Experimental: 0.02	Not available	Not calculated

Table 2 *(continued)*.

Vassallo 2004+	CT	825	ID bracelet, Environmental review	1 year	(per 100 obd) Control: 1.15 Experimental: 1.23	Control: 20.2 Experimental: 14.2	Not Significant

(+) Similar Studies to Oliver's Meta-analysis (2007)

Table 3

Oliver's Meta-Analysis: Comparison of 13 Studies by Design, Interventions, Outcome Variables, and Results

First Author Year	Design	Intervention Type	Patient Outcome Variables		Results	
			Number of Falls	Fallers (%)	Falls/Rate Ratio (95% CI)	Fallers/Relative Risk (95% CI)
Barry 2001	Pre and post test	Equipment/ environmental, hip protector, restraint review	Control: 71; Experimental: 56	Control: 25.0; Experimental: 20.9	0.72 (0.50 to 1.02)	0.84 (0.56 to 1.25)
Brandis 1999	Retrospective observational cohort	Hip protector, restraint review	Control: 260; Experimental: 258		0.93 (0.78 to 1.10)	N/A**

Table 3 *(continued)*.

Fonda 2006	Pre and post test	Equipment/ environmental restraint review	Control: 352; Experimental: 255		0.62 (0.52 to 0.72) Significant	N/A**
Haines 2004*	RCT	Hip protector	Control: 149; Experimental: 105	Control: 22.5; Experimental: 17.4	0.69 (0.54 to 0.88) Significant	0.78 (0.56 to 1.06)
Healey 2004*	RCT, Paired cluster	Equipment/ environmental restraint review	Control: 319; Experimental: 180		0.59 (0.25,1.37) Significant	
Hoffman 2003	Pre and post test	Equipment/ environmental restraint review			0.93 (0.73 to 1.19)	

Table 3 *(continued)*.

Kilpack 1991	Pre and post test	Equipment/ environmental	Control: 116; Experimental: 111		0.94 (0.72 to 1.21)	N/A**
Mayo 1994*	RCT		Control: 33; Experimental: 38	Control: 30.4 Experimental: 41.5	1.15 (0.72 to 1.84)	1.36 (0.86 to 2.16)
Mitchell 1996	Pre and post test	Equipment/ environmental	Control: 42; Experimental: 21		0.56 (0.33 to 0.94)	N/A**

Table 3 *(continued)*.

Reuben 1995	RCT	Equipment/ environmental		Control: 10.1; Experimental: 12	N/A**	1.18 (0.93 to 1.49)
Savage 2001	Pre and post test	Equipment/ environmental	Control: 11; Experimental: 1	Control: 39.1; Experimental: 43	0.09 (0.01 to 0.70)	0.11 (0.02 to 0.81)
Vassallo 2004*	RCT, Open cluster	Equipment/ environmental restraint review	Control: 170; Experimental: 72	Control: 20.2; Experimental: 14.2	1.07 (0.25 to 4.65)	0.70 (0.15 to 3.20)

* Similar Studies to Coussement's Meta-analysis (2007)

** = N/A = not available

Table 4

Chang's Meta-Analysis: Comparison of Nine Studies by Sample, Design, Interventions, and Results

First Author Year	Sample	Design with Allocation Concealment (Yes or No)	Interventions	Results
Cumming 1999	530	RCT/Yes	Environmental changes (Enrolled = 264; Completed = 198)	Proportion (Enrolled = 45 %; Completed = 36 %) with at least 1 fall event in 12 months
Day 2002	1090	RCT/No	Environmental changes (Enrolled = 136; Completed = 58); Exercise and environmental changes (Enrolled = 135; Completed = 61)	Proportion with at least 1 fall event in 18 months; Environmental changes 57 % (fall rate ratio); Combined exercise and environmental changes 53 % (fall rate ratio)

Table 4 *(continued)*.

El-Faizy 1994	28	RCT/No	Environmental changes (Enrolled = 14; Completed = 13)	Number of falls (Enrolled = 5; Completed = 9) in 9 months
Hornbrook 1994	3182	RCT/No	Environmental changes (Enrolled =1611; Completed = 1455)	Number of falls (2084) in 22.8 months and number of falls (1730) in 22 months
Pardessus 2002	60	RCT/No	Environmental changes (Enrolled = 30; Completed = 24)	Proportion (50%; 43%) with at least 1 fall event in 12 months
Salkeld 2000	530	RCT/No	Environmental changes (Enrolled = 264; Completed = 257)	Number of falls (Enrolled = 324; Completed = 226) in 12 months

Table 4 *(continued)*.

Steinberg 2000	252	RCT/No	Fall Protective Bundle [1]: Education/group advisement), exercise, and environmental changes (Enrolled = 61; Completed = 60)	Incidence rate 3.62/100 person months of observation
			Fall Protective Bundle [2]: Education/group and individual advisement), exercise, and environmental changes (Enrolled = 59; Completed = 57)	Incidence rate 3.88/100 person months of observation

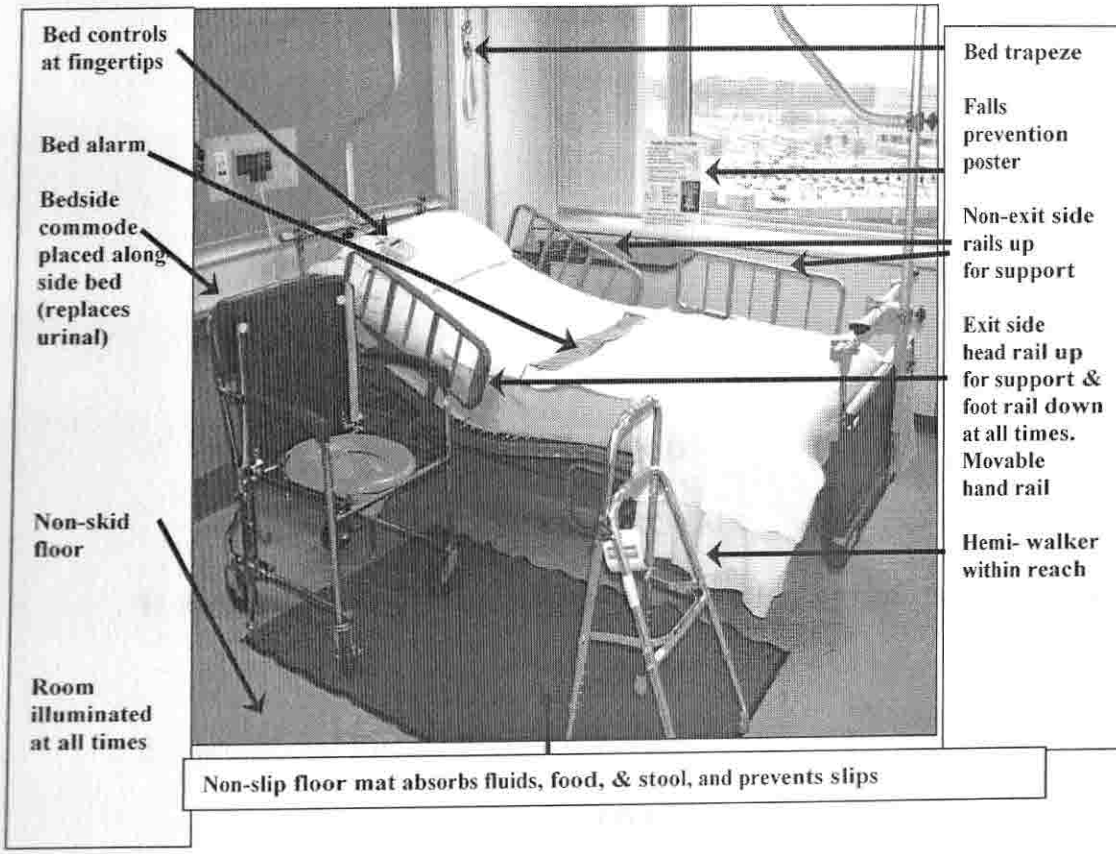
Table 4 *(continued)*.

Stevens 2001	1879	RCT/No	Environmental changes (Enrolled = 635; Completed = 524)	Number of falls (Enrolled = 437; Completed = 899) in 12 months
Van Haastregt 2000	316	RCT/No	Environmental changes and falls risk assessment and management (Enrolled = 159; Completed = 120)	Proportion (44 %; 50 %) with at least 1 fall event in 12 months

APPENDIX C

MODEL: FALL PREVENTION ROOM (FPR)

Model: Fall Prevention Room (FPR)



APPENDIX D

AGENCY APPROVALS

1. Institutional Review Board Approval Letter: Baylor College of Medicine (BCM)
2. Institutional Review Board Approval Letter: Texas Woman's University (TWU)
3. Human Research & Development Approval Letter: Michael E. DeBakey Veterans Affairs Medical Center (MEDVAMC)

1. Institutional Review Board Approval Letter: BCM

April 02, 2008

BCM
Baylor College of Medicine

PAMELA WILLSON
BAYLOR COLLEGE OF MEDICINE
NEUROLOGY

Baylor College of Medicine
Office of Research
One Baylor Plaza, 600D
Houston, Texas 77030
Phone: (713) 798-6970
Fax: (713) 798-6990
Email: irb@bcm.tmc.edu

H-20697 - ENVIRONMENTAL EFFECTS ON INCIDENCE OF FALLS

APPROVAL VALID FROM 4/2/2008 TO 3/18/2009

Dear Dr. WILLSON

The Institutional Review Board for Human Subject Research for Baylor College of Medicine and Affiliated Hospitals (BCM IRB) is pleased to inform you that the research protocol and consent form(s) named above were approved.

The study may not continue after the approval period without additional IRB review and approval for continuation. You will receive an email renewal reminder notice prior to study expiration; however, it is your responsibility to assure that this study is not conducted beyond the expiration date.

Please be aware that only IRB-approved informed consent forms may be used when written informed consent is required.

Any changes in study or informed consent procedure must receive review and approval prior to implementation unless the change is necessary for the safety of subjects. In addition, you must inform the IRB of adverse events encountered during the study or of any new and significant information that may impact a research participants' safety or willingness to continue in your study.

The BCM IRB is organized and operated according to guidelines of the International Council on Harmonization, the United States Office for Human Research Protections and the United States Code of Federal Regulations and operates under Federal Wide Assurance No. 00000286, issued April 30, 2001. Affiliated hospitals include: the Michael E. Debakey Veterans Affairs Medical Center, St. Luke's Episcopal Hospital, The Methodist Hospital, Texas Childrens Hospital, Texas Institute for Rehabilitation and Research, and the Harris County Hospital District.

Sincerely yours,

Mary Michele Mariscalco

MARY M MARISCALCO, M.D.

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Full AAHRPP Accreditation

2. Institutional Review Board Approval Letter: TWU

TWU
TEXAS WOMAN'S UNIVERSITY
DENTON DALLAS HOUSTON

Office of Research
6700 Fannin Street
Houston, TX 77030-2343
713-794-2480 Fax 713-794-2488

April 8, 2008

Ms. Huberta Cozart
College of Nursing - Rae Langford Faculty Advisor
6700 Fannin Street
Houston, TX 77030

Dear Ms. Cozart:

Re: "Enviornmental effects on incidence of falls in the hospitalized elderly"

The above referenced study has been reviewed by the TWU Institutional Review Board (IRB) and was determined to be exempt from further review.

Any changes in the study must receive review and approval prior to implementation unless the change is necessary for the safety of subjects. In addition, you must inform the IRB of adverse events encountered during the study or of any new and significant information that may impact a research participant's safety or willingness to continue in your study.

Sincerely,

William P. Hanten

Dr. William P. Hanten, Chair
Institutional Review Board - Houston

VA FORM
MAR 1989 **2105**

Department of **Memorandum**

Veterans Affairs

Date: May 18, 2007

From: Chair, Research & Development Committee (580/151)

Subj: Title: Environmental Effects on Incidence of Falls

VA ID Number: 07D13.H	Please this number to identify the protocol when communicating with the VA Research Office.

To: Pamela Willson, PhD, RN

At the April 26, 2007 Research and Development Committee meeting, the above referenced project was approved with conditions. Those conditions have since been met; the protocol is **APPROVED IN FULL** and you may begin the research.

PLEASE MAKE NOTE OF THE FOLLOWING STIPULATIONS

1. **Documenting patient enrollment**
   When enrolling patients in this project you do NOT need to use the "Research Protocol Entry Note" title in order to flag this patient in CPRS as being enrolled in an interventional research study. However, research notes should be entered in CPRS.

2. **Pharmacy Service**
   If the research involves an investigational drug, please send a copy of the complete protocol, prepared for or by the study sponsor, to Nancy Hewitt or Tai Dinh Vu in Pharmacy Service (mail code 119). **There is a charge for the use of Pharmacy Service. See the VA Research Webpage for details.**

3. **Reporting adverse events, deviations and exceptions**

All adverse events, deviations from protocol, and exceptions to the human studies protocol must be reported to the IRB through BRAIN. Death or substantive events should also be reported directly to the VA Research Office.

4. **People working on this project must be trained and credentialed.**

   All individuals involved in human research, whatever their role, must have annual training in human research (IRB) and Good Clinical Practice. The PI is responsible for verifying that all members of the research team are able to perform their assigned duties.

5. **National Clinical Trials Registry**

   Please ensure that your clinical trial project is registered with the National Library of Medicine's Clinical Trials Registry BEFORE the first patient is enrolled into the study. Remember, if you do not register your study, you risk not having the ability to publish your results in certain journals Registry information and guidelines are found at website: *http://www1.va.gov/resdev/resources/ORD_Admin/clinical_trials/default.cfm.*

6. **To keep this project active**

   Renew it on an annual basis by completing the project information sheets when these are sent to you. You are also responsible for renewing the human studies and animal protocols through BRAIN on an annual basis. Conducting human research without IRB approval will affect your standing in the VA.

7. **To make changes to the protocol**

   Changes to this protocol that involve humans, animals, biohazard materials, or radioactive materials must be approved before they are implemented. Changes in animal or human research should be submitted as an amendment to the relevant protocol through BRAIN. Changes in biohazard and/or radiation should be noted on the appropriate update application form and submitted to the Research Office, Bldg. 110, room 306.

8. **Acknowledging VA Research Support and VA employment**
   Publications, presentations, media interviews, and similar activities must acknowledge the support of the Department of Veterans Affairs in this research. Acknowledgement is expected not only for direct research funding from the VA, but also for indirect support such as use of VA resources (patients, laboratories, and/or clinical facilities), and the investigator's full-time, part-time, or without compensation (WOC) appointment.

9. You are responsible for any ethical breaches in the conduct of this research and these may affect your ability to do research with the VA in the future.

ANITA DESWAL, MD

APPENDIX E

MORSE FALL SCALE (MFS)

Morse Fall Scale (MFS)

(Adapted with permission, SAGE Publications)

The Morse Fall Scale (MFS) is a rapid and simple method of assessing a patient's likelihood of falling. A large majority of nurses (82.9%) rate the scale as "quick and easy to use," and 54% estimated that it took less than 3 minutes to rate a patient. It consists of six variables that are quick and easy to score, and it has been shown to have predictive validity and interrater reliability. The MFS is used widely in acute care settings, both in the hospital and long term care inpatient settings.

Item	*Scale*	*Scoring*
1. History of falling; immediate or within 3 months	No 0 Yes 25	______
2. Secondary diagnosis	No 0 Yes 15	______
3. Ambulatory aid Bed rest/nurse assist Crutches/cane/walker Furniture	0 15 30	______
4. IV/Heparin Lock	No 0 Yes 20	______
5. Gait/Transferring Normal/bedrest/immobile Weak Impaired	0 10 20	______
6. Mental status Oriented to own ability Forgets limitations	0 15	______

APPENDIX F

WRITTEN CONSENT FORM

Department of Veterans Affairs **VA RESEARCH CONSENT FORM** HIPAA Compliant

Subject Name: ______________________ **Date:** __________

Subject Initials: ______________________

Principal Investigator: PAMELA WILLSON **VAMC:** __________

H-20697 - ENVIRONMENTAL EFFECTS ON INCIDENCE OF FALLS

Background

When a patient is admitted to a hospital in the US, accidental falls may happen. Some studies found that placing safety devices in the hospital room and bathroom would prevent falls. We want to prevent accidental falls by using some additional special equipment like a shower mat in the bathroom or a special bed that easily adjusts to different heights.

This research study is sponsored by Baylor College of Medicine.

Purpose

This study will look into how falls may be prevented for hospitalized patients by using additional safety equipment.

Procedures

You will be one of approximately 64 subjects to be asked to participate in this study.

The research will be conducted at the following location(s): Baylor College of Medicine, Michael E. DeBakey Veterans Affairs Medical Center.

When you were admitted to the unit, the nurse checked to see if you were at risk for falls. Since falling is a concern for you, we are inviting you to take part in this study. If you agree to join, you will have a 50% chance of being placed in a room with extra safety equipment.

If you want to take part in this study, you will be asked to sign a consent form. Then a team member will visit you for seven days. We will ask you questions, such as your age, birthday, race, address, and about your health. In addition, you will be asked about any slips, trips, or actual falls that might have happened while you are in the hospital. The interviews will be short, about 2-5 minutes each day. You can stop the interviews or ask the researcher to come back at another time. The study visits will not interfere with your care.

You can see and get a copy of your research related health information. Your research doctor may be able to provide you with part of your information while the study is in progress and the rest of your information at the end of the study.

Potential Risks and Discomforts

There is small chance that you may feel uncomfortable when asked about personal information or that you may become tired. If this should occur you may stop the interview or stop being in the study at any time. There may be a slight risk of loss of confidentiality and privacy. However, we will careful with all information and keep all documents locked in the research office.

Department of Veterans Affairs

VA RESEARCH CONSENT FORM

HIPAA Compliant

Subject Name: ______________________ **Date:** __________

Subject Initials: ______________________

Principal Investigator: PAMELA WILLSON **VAMC:** __________

H-20697 - ENVIRONMENTAL EFFECTS ON INCIDENCE OF FALLS

Potential Benefits

The benefits of participating in this study may be: 1) knowing about your risk for falling, 2) knowing about steps to prevent falls, and 3) by receiving daily visits from the research team. . However, you may receive no benefit from participating.

Alternatives

You may choose to not participate in this study.

Subject Costs and Payments

You will not receive any payment for being in the study.

Subject's Rights

Your signature on this consent form means that you have received the information about this study and that you agree to be a part of the study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

The investigator or sponsor may decide to stop you from taking part in this study at any time. You could be removed from the study for reasons related only to you (for example, if you move to another city, if you do not take your study medication, or if you have a serious reaction to your study medication) or because the entire study is stopped. The sponsor may stop the study at any time.

There may be unknown risks/discomforts involved. Study staff will update you in a timely way on any new information that may affect your health, welfare, or decision to stay in this study.

If you are injured because of this study, you will receive medical care that you or your insurance will have to pay for just like any other medical care. You will not be paid for the injury.

Your Health Information

We may be collecting health information that could be linked to you (protected health information). This protected health information might have your name, address, social security number or something else that identifies you attached to it. Federal law wants us to get your permission to use your protected health information for this study. Your signature on this form means that you give us permission to use your protected health information for this research study.

Department of Veterans Affairs **VA RESEARCH CONSENT FORM** HIPAA Compliant

Subject Name: ______________________ **Date:** ________

Subject Initials: ______________________

Principal Investigator: PAMELA WILLSON **VAMC:** ________

H-20697 - ENVIRONMENTAL EFFECTS ON INCIDENCE OF FALLS

If you decide to take part in the study, your protected health information will not be given out except as allowed by law or as described in this form. Everyone working with your protected health information will work to keep this information private. The results of the data from the study may be published. However, you will not be identified by name.

People who give medical care and ensure quality from the institutions where the research is being done, the sponsor(s) listed in the sections above, representatives of the sponsor, and regulatory agencies such as the U.S. Department of Health and Human Services will be allowed to look at sections of your medical and research records related to this study. Because of the need for the investigator and study staff to release information to these parties, complete privacy cannot be guaranteed.

The people listed above will be able to access your information for as long as they need to, even after the study is completed.

If you decide to stop taking part in the study or if you are removed from the study, you may decide that you no longer allow protected health information that identifies you to be used in this research study. Contact the study staff to tell them of this decision, and they will give you an address so that you can inform the investigator in writing. The investigator will honor your decision unless not being able to use your identifiable health information would affect the safety or quality of the research study.

The investigator, PAMELA WILLSON, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: PAMELA WILLSON at 713-794-8538 and Bette Cozart at (713) 797-7071during the day or (713) 819-3137 (cell phone)after hours.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The IRB office number is (713) 798-6970.

You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled. Your participation will not affect the way you now pay for medical care at the VAMC.

Department of Veterans Affairs

VA RESEARCH CONSENT FORM

HIPAA Compliant

Subject Name: ____________________ **Date:** ________

Subject Initials: ____________________

Principal Investigator: PAMELA WILLSON **VAMC:** ________

H-20697 - ENVIRONMENTAL EFFECTS ON INCIDENCE OF FALLS

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

Subject	Date	
Legally Authorized Representative	Date	Relationship to Subject
Investigator or Designee Obtaining Consent	Date	
Witness	Date	

APPENDIX G

LIST OF MEDICAL AND SURGICAL DIAGNOSES

LIST OF MEDICAL AND SURGICAL DIAGNOSES

1. Knee Arthroplasty
2. Hip Arthroplasty
3. Spinal Cord Disease
4. CVA
5. UTI
6. Closed Fracture
7. CABG
8. Neurosyphillis
9. Lower Extremity Weakness
10. Seizure
11. Osteoarthritis
12. Low Back Pain
13. Rectal Bleed
14. Superior Sagittal Sinus Thrombosis
15. Heel Arthralgia
16. Joint Pain: Ankle & Foot
17. Lumbar Decompression
18. Spastic Hemiplegia
19. CAD
20. Major Depression
21. Vertebrectomy
22. Alcohol Abuse
23. Osteomyelitis
24. Laminectomy
25. TIA
26. Demyelinating Neuropathy
27. Muscle Weakness
28. Myasthenia Gravis
29. Anemia
30. Bell's Palsy
31. Multiple Sclerosis
32. Carotid Angioplasty
33. Diplopia
34. Sleep Apnea
35. Vertigo
36. Myelopathy
37. COPD
38. Bursitis
39. Dilantin Toxicity
40. Vision Loss
41. Peripheral Neuropathy